Jennifer,

The updated documents (b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image002.png@01D8BEB7.91E5F8D0]<http://secure-web.cisco.com/1arDUGkZgyJ2rFvnW3gifJPFF2SviGG0mjP0p72PawP-87nC3XpexgKW4VgalC2kB5U1_Po-Z8NwTu0RH9PF7Gr5gx8zlPNFbXvhEaJNGEGH2MWeQ0kgstvvIbdqmnnfMADM6B1g3Fagis36MB81_aIxDdspXWb49aBHFKbcbseqUBZJEPWdgkq5gaVE22jQe/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/13xHjnhRIdDjnGGnH7R5ZqNkixVsz99Ygt1mB1WfAdLpwdQ9Y9o5x7oL3bln5n_vH5FV2m5DFLnSJiJPKUyAc0jFxynkeZZjrPwRFPm78Aeozdv0OYgLGZ2mjjJD8K8g1283heGZTQdR_i2weLAFsGznqBi2tH_ahEZQjm5EoGjVJqVSOG_td7c7SDcfsvSk3/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1arDUGkZgyJ2rFvnW3gifJPFF2SviGG0mjP0p72PawP-87nC3XpexgKW4VgalC2kB5U1_Po-Z8NwTu0RH9PF7Gr5gx8zlPNFbXvhEaJNGEGH2MWeQ0kgstvvIbdqmnnfMADM6B1g3Fagis36MB81_aIxDdspXWb49aBHFKbcbseqUBZJEPWdgkq5gaVE22jQe/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image010.png@01D8BEB7.91E5F8D0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=aVS4ag2WlCnvmLd9enMuIzb3QZYVeEr1qJesctXjmvE%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/13xHjnhRIdDjnGGnH7R5ZqNkixVsz99Ygt1mB1WfAdLpwdQ9Y9o5x7oL3bln5n_vH5FV2m5DFLnSJiJPKUyAc0jFxynkeZZjrPwRFPm78Aeozdv0OYgLGZ2mjjJD8K8g1283heGZTQdR_i2weLAFsGznqBi2tH_ahEZQjm5EoGjVJqVSOG_td7c7SDcfsvSk3/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=aVS4ag2WlCnvmLd9enMuIzb3QZYVeEr1qJesctXjmvE%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image016.jpg@01D8BEB7.91E5F8D0]
<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFDA%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=t22yf68B85O7alCGemh2y9YyUt39zl8TLYLrMEmdaB8%3D&reserved=0>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Jennifer,

Email received and we'll start working on this right away. I'll let you know if any follow-up questions.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Thursday, August 04, 2022 12:06 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty - (b)(4) Interactive Request - Response due COB August 10, 2022

Good morning Justin,

(b)(4)

I'm requesting the above additional information **by COB Wednesday August 10, 2022.**

I'm available if there are questions regarding this request.

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Investigations Compliance Statements

(b)(4)

(b)(6)

Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine

8/10/2022

Date

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8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

The following table includes a list of all investigators for each clinical study.

Investigator	Study Title	Employment Status Related to DePuy and Prosidyan	Form
(b)(6)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Prosidyan™

Memo

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2022

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	(b)(6)	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

(b)(6)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2022

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning (b)(6) _____, who participated
Name of clinical investigator

as a clinical investigator in the submitted study, (b)(4) _____
Name of clinical study

(b)(4) _____ submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

- ☒ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- ☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- ☒ any proprietary interest in the product tested in the covered study held by the clinical investigator;
- ☒ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

(b)(6)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2022

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning (b)(6) _____, who participated
Name of clinical investigator

as a clinical investigator in the submitted study (b)(4)
Name of clinical study

(b)(4) is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☒ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

(b)(6)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2022

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning (b)(6) _____, who participated
Name of clinical investigator

as a clinical investigator in the submitted study (b)(4) _____
Name of

_____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☒ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

(b)(6)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
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TO BE COMPLETED BY APPLICANT

The following information concerning (b)(6) _____, who participated
Name of clinical investigator

as a clinical investigator in the submitted stud (b)(4)
Name of

(b)(4) _____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☒ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

(b)(6)

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Department of Health and Human Services
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September 27, 2022</br></br>

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K222276 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

14. STERILIZATION AND SHELF LIFE

The sterilization and shelf-life of the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty are identical to the predicate devices (K201605, K170306).

14.1 Sterilization

14.1.1 EIT Cellular Titanium® Cages

The following information was provided and reviewed by FDA in K201605.

There have been no changes to the sterilization method since the prior submission (K201605). The EIT Cellular Titanium® Cages are provided sterile and are sterilized by gamma irradiation.

The sterilization parameters are provided below (identical to K201605):

- **Sterilization Method:** Gamma radiation
- (b)(4)
- **Method Used to validate the sterilization cycle:** Sterilization validations were successfully conducted in accordance with ISO11137-1 requirements.
- **Sterility Assurance Level:** SAL of 10^{-6}

14.1.2 FIBERGRAFT® BG Putty

The following information was provided and reviewed by FDA in K170306.

Per FDA's draft guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Final Guidance," issued February 11, 2016, the following information is supplied. Consistent with FDA's "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" and similar to the BG Putty predicate, the subject BG Putty will be provided sterile for single use with a sterility assurance level (SAL) of 10^{-6} via a validated gamma radiation cycle.

There have been no changes to the sterilization method since the prior submission (K170306). The FIBERGRAFT® BG Putty are provided sterile and are sterilized by gamma irradiation. The gamma radiation sterilization cycles are designed and validated per ISO 11137-2:2013. The BG (b)(4)

The sterilization parameters are provided below (identical to K170306):

- **Sterilization Method:** Gamma radiation
- **Radiation Dose:** (b)(4)
- **Method Used to validate the sterilization cycle:** $VD_{max}^{32.5}$, as outlined in ISO11137-2:2013-Sterilization of health care products-Radiation-Part2: Establishing the sterilization

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dose and AAMI TIR 33:2005. Sterilization of health care products-Radiation-Substantiation of a selected sterilization dose Method VD_{max}.

- **Sterility Assurance Level:** SAL of 10^{-6}

The sterilization dose, bioburden method and sterility test method per ISO 11137-2 was established in K170306. No changes have been made since K170306 to the sterilization process or to the device that could affect the effectiveness of the sterilization process.

14.2 Shelf Life

The shelf life of the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty are identical to the predicate devices (K201605, K170306 respectively).

14.2.1 EIT Cellular Titanium® Cages

The following information was provided and reviewed by FDA in K201605.

There have been no changes to the EIT Cellular Titanium® Cages since the prior submission (K201605) that would impact the shelf-life of the implants. The EIT Cellular Titanium® Cages

(b)(4)

14.2.2 FIBERGRAFT® BG Putty

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000099

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(b)(4)

14.3 Packaging

The packaging of the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty are identical to the predicate devices (K201605, K170306).

14.3.1 EIT Cellular Titanium® Cages

The following information was provided and reviewed by FDA in K201605.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000100

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

14.3.2 FIBERGRAFT® BG Putty

The following information was provided and reviewed by FDA in K170306.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000101

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) (also attached). We appreciate the continued interaction and will remain on standby for questions as they arise.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,

Justin

[cid:image002.png@01D8C81F.DBDB3FB0]<http://secure-web.cisco.com/1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ustin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C646de0e164334b6fa3ed08da902a9383%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637980809805223253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=icP3JqLxOvxOUKD5mVf2N%2BnFGCQiLN5p2lXwf0bMgNU%3D&reserved=0
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image006.png@01D8C81F.DBDB3FB0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C646de0e164334b6fa3ed08da902a9383%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637980809805223253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YBk7QkTPBGO2ioFUitPI4EwNfrWAJIeESon8lCkmrfM%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C646de0e164334b6fa3ed08da902a9383%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637980809805223253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YBk7QkTPBGO2ioFUitPI4EwNfrWAJIeESon8lCkmrfM%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
DEPUY SPINE INC 325 PARAMOUNT DRIVE RAYNHAM MA 02767-0350 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3238	Karin McDonough 2.1 E-MAIL ADDRESS kmcdono3@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 508-977-3851 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-828-3797

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 14-Jul-2022

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

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Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

[cid:image003.png@01D8D8CB.8AB63FB0]<http://secure-web.cisco.com/1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8D8CB.8A974600]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<http://secure-web.cisco.com/1NCywdwec0hmbg4QfZv592mOqJ850t6OGY4a9bhC4WnQ625tnb1NRDj8azRDIJHYDOW84DqGyNSqUC7UI2mczjo4vTpasiELr9are18909HRZ62b2XkkVQf7hLPljPHFIQwGdGZLqW7fj7hAvoDxjMxC-eQHF44_DeIedStzndZ6inA7StnsVApslm2AsXKZfmMFKgaqggexRzjmIr7UpWA/http%3A%2F%2Fwww.eventleaf.com%2Fe%2FNASSnetworking>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. The (b)(4) are attached to this email for your review.

Thanks,

Justin

[cid:image007.png@01D8D8CB.8AB63FB0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981164112%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gN18pG0poyqW0njZ%2FqqKqsink8WnEwGWEw94pkMohBg%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dMtpztD4aXZhAUtxppCDzG94ER1vwlRI1kw2hLVWsAY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

(b)(4)

Thanks,

Justin

[cid:image009.png@01D8D8CB.8AB63FB0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

[cid:image009.png@01D8D8CB.8AB63FB0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5h%2BogPYsUJaOfCE%2BtSo9cxzBVJZwJVIuR6ksX5Qq4Ls%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

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Washington, DC 20001

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6M

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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7C%7C%7C&sdata=myIoqRnOoz5Yji4C107jv0gtyVhsKh51adDd%2FFcKNJA%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981945248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gTqsRChaTBCXGYdD3jGbPYS1hmU1fLGFTMOcmxQS81s%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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CONDUIT™ ALIF System

(b)(4)

Surgical Technique

DePuy Synthes

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CONDUIT™ Cervical System

(b)(4)

Surgical Technique

DePuy Synthes

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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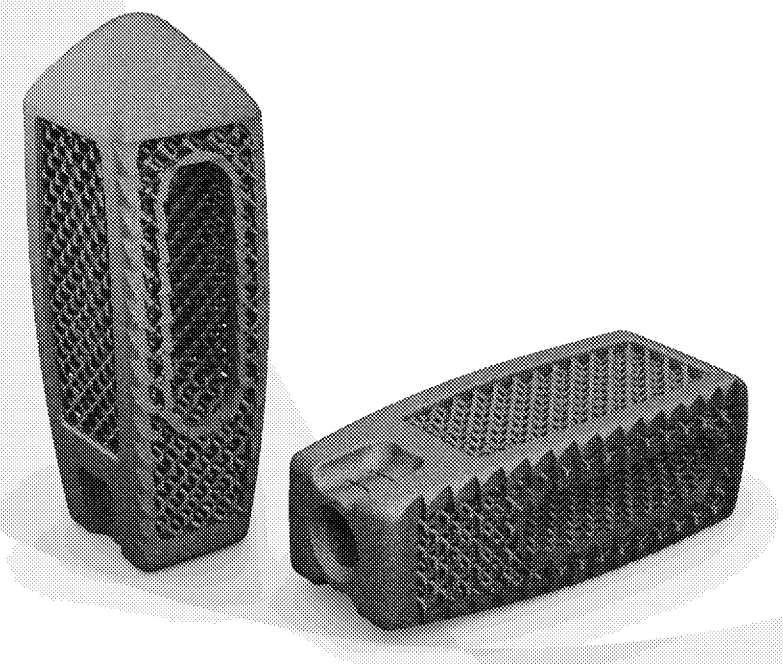
CONDUIT™ Straight TLIF / PLIF System

(b)(4)

Surgical Technique



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CONDUIT™ Curved TLIF System

(b)(4)

Surgical Technique

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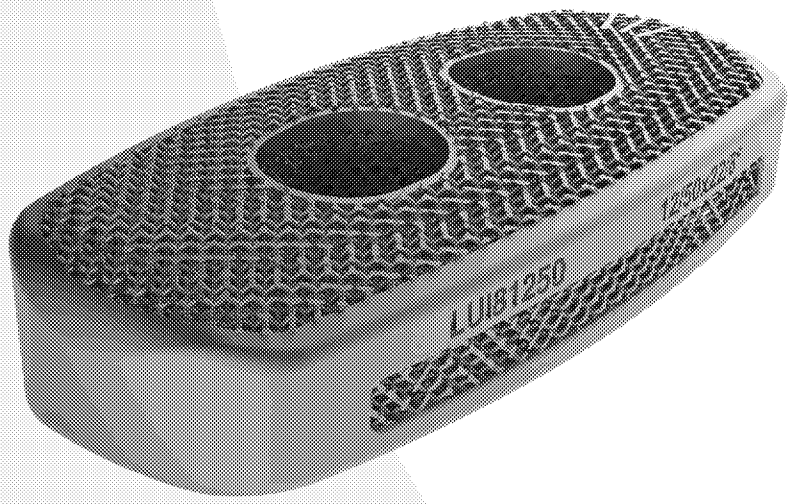
CONDUIT™ Lateral System

(b)(4)

Surgical Technique



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5. 510(k) SUMMARY

(b)(4)

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510(k) SUMMARY

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Jennifer,

Thank you for the opportunity to interact on these questions. The formal response is attached to this email. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image008.png@01D8AC9B.98E718E0]<http://secure-web.cisco.com/1TPKmFEH7oWB7dczHySTFLSgCgf6vQFN7Fsa0j-Hewl3X8VwxjBeQGWo89G1dNSomWKgOg7Q578tVwQ7F4bU4J4qVW8WtpRhWlcTNEkBr2ZZmWHXFrl6__Fqxkz3E1x3HWNoGlOt5cqem2XUjTq0MQ5ODE4Ktr6iSpI7o15mzGoPyOkyv-ZHANEqCdAi_WgAEftadlb6ZXzYf_0ohfLVMCFQ_fuyYDSlqzK8qRKqYTQM/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1jlXZ7Uwe2J95L8UBJER76-hvj76TUcpCyqeednVZG91oBwo9Sj-07Qmtni5X-jnT2FErP8WPPpYieH1N-rlRI9HYtM9sPRnV-s3huo3WTIYcQLGeNp-vu6b4DBwZ8zgnZH7atYtYztCewTHfT1oCCwBU-W6z1qvYICfjBIZBoLJD-1ff4Pm5av5VSPDeROmYOduh3St7Rqeb6R6kccoYu_KCE1dd1njqSMQDSIzXQao/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1TPKmFEH7oWB7dczHySTFLSgCgf6vQFN7Fsa0j-Hewl3X8VwxjBeQGWo89G1dNSomWKgOg7Q578tVwQ7F4bU4J4qVW8WtpRhWlcTNEkBr2ZZmWHXFrl6__Fqxkz3E1x3HWNoGlOt5cqem2XUjTq0MQ5ODE4Ktr6iSpI7o15mzGoPyOkyv-ZHANEqCdAi_WgAEftadlb6ZXzYf_0ohfLVMCFQ_fuyYDSlqzK8qRKqYTQM/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Monday, August 08, 2022 12:23 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: K222276 - Clarifying question

Hello Justin,

I have one minor question in addition to my recently issued request for information.

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(b)(4)

Thank you,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hello Justin,

I have one minor question in addition to my recently issued request for information.

(b)(4)

Thank you,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Hi Justin,

Thanks for confirming receipt. I'll look forward to your response.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Thursday, August 4, 2022 12:36 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty - RTA Checklist Interactive Request - Response due COB August 10, 2022

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Jennifer,

Email received and we'll start working on this right away. I'll let you know if any follow-up questions.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Thursday, August 04, 2022 12:06 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty (b)(4) Interactive Request - Response due COB August 10, 2022

Good morning Justin,

(b)(4)

I'm requesting the above additional information **by COB Wednesday August 10, 2022.**

I'm available if there are questions regarding this request.

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Thanks! Despite my OOO message, still monitoring for FDA emails so let me know if anything else we can do.

Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

202.552.5804

-------- Original message --------

From: "Houck, Jennifer" <Jennifer.Houck@fda.hhs.gov>

Date: 10/13/22 8:58 AM (GMT-06:00)

To: Justin Eggleton <jeggleton@mcra.com>, "Desjardins, Philip [JJCUS]" <pdesjard@ITS.JNJ.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thanks for this additional piece of information. We appreciate it.

Have a great rest of your week,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Monday, October 10, 2022 8:47 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,

Justin

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Vb55CgLnxYUBpBA%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

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If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP
here<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-
web.cisco.com%2F1VnBULoz-YtQfJLPockl8ERjsoNfmkP-
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Friday, October 07, 2022 9:21 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Thursday, October 6, 2022 7:05 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Web: http://secure-web.cisco.com/1EDK7_owXHuaNG_3wgPSOIbU5opeUMc8V-SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-BACzfH0a8Bi78WEmpcc6XnP2J1iunjJELoYCXGNF0yOXI9OhjmpLztB1hv8SGoO7W5_be48H7ytrVNYg4C_ESbNQJByjc74OCwCUAYdQ/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279367488%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2NBKH92gSisGdLjR9dxgaTJ5NsjJ3psmMTJ0YVGoo9s%3D&reserved=0>

[cid:image004.jpg@01D8DEEA.49F20160]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1vH7QKmXvtYr0aNjzCQzPB27CtXUwmYWSj8K3mKl4izP2tOwE5eeDeRVQ44vWkYajT0lQtT1mFLsvoqx5b1P2uXeWA3f5ld0q_nFnGQs1Dm0XnchAIgr3NOTvKm9dFI2MpMedc1H0odlhJHsG9z32ctTi4ztZ3RDWqtKSADk1VSL7HGRMsov0cDHC6i9yMQQIUUDNHx9ZuV8RpqpdhJ6vDzsDYQP3FxMNH2UI9NoaoHE%2Fhttp%253A%252F%252Fwww.eventleaf.com%252Fe%252FNASSnetworking&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279367488%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=CIPyc6CAGtwCrCRGdUOzjawRR81Sg9JVnseiZsXjjE4%3D&reserved=0>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Thursday, October 06, 2022 4:24 PM

To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. Would it be possible to point me in the

(b)(4)

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1EDK7_owXHuaNG_3wgPSOIbU5opeUMc8V-SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-BACzfH0a8Bi78WEmpcc6XnP2J1iunjJELoYCXGNF0yOXI9OhjmpLztB1hv8SGoO7W5_be48H7ytrVNYg4C_ESbNQJByjc74OCwCUAYdQ/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279367488%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=AJWaiSyT5JMBc8DaCbnPFX3spPv%2BIRGVZw9L7hdSEJU%3D&reserved=0>

[cid:image004.jpg@01D8DEEA.49F20160]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

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To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4) are attached to this email for your review.

Thanks,

Justin

[cid:image006.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279367488%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=TBtbnu7DlwXbNqEie8wuAmsIRmc%2FKu5rBHfFRblR0IM%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1EDK7_owXHuaNG_3wgPSOIbU5opeUMc8V-SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-BACzfH0a8Bi78WEmpcc6XnP2J1iunjJELoYCXGNF0yOXI9OhjmpLztB1hv8SGoO7W5_be48H7ytrVNYg4C_ESbNQJByjc74OCwCUAYdQ/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279523716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5TRkz44kCyEJbXULene10PruJhKVSiZC%2BHFAaouUJcQ%3D&reserved=0>

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. The responses

(b)(4)

Questions? Contact FDA/CDRH/OCE/DDM CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Justin

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ustin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

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SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) (also attached). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

[cid:image008.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279523716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5Ra88lugF%2F2XuCurD9RbOO0R10fxBHa%2BRNANl7ulV0o%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1EDK7_owXHuaNG_3wgPSOIbU5opeUMc8V-SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-BACzfH0a8Bi78WEmpcc6XnP2J1iunjJELoYCXGNF0yOXI9OhjmpLztB1hv8SGoO7W5_be48H7ytrVNYg4C_ESbNQJByjc74OCwCUAYdQ/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279523716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5Ra88lugF%2F2XuCurD9RbOO0R10fxBHa%2BRNANl7ulV0o%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1EDK7_owXHuaNG_3wgPSOIbU5opeUMc8V-SN0YmTUDAwnX949m28QYrXpyWHmH7T8lfrYuP_t3X3DHzYsFkit6WfaoKUJpmcLYuM8iclnbOvFA-BACzfH0a8Bi78WEmpcc6XnP2J1iunjJELoYCXGNF0yOXI9OhjmpLztB1hv8SGoO7W5_be48H7ytrVNYg4C_ESbNQJByjc74OCwCUAYdQ/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C5a0a93792bcc4e8ab01708daad230767%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638012663279679956%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=M8yoxSFchUUfPq9YDOqaY4lVsstPJ59tseT2efOtNX8%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024
FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Eggleton

Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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5. 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUMMARY

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

The requested information is presented (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Friday, October 07, 2022 9:21 AM
To: Justin Eggleton <jeggleton@mcra.com>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Thursday, October 6, 2022 7:05 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Thursday, October 06, 2022 4:24 PM
To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask (b)(4) (b)(4) If that is not located within your submission, can you please provide that information?

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. **(b)(4)**

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience a (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Devices

The purpose of this Traditional 510(k) is to demonstrate that the subject device is substantially equivalent to the predicate device(s) for the purpose of introducing to interstate commerce. The EIT Cellular Titanium® Cages are substantially equivalent in device indications, manufacturing process, surgical approach, principles of operation, design and performance to the following devices:

- *Primary Predicate:* DePuy Synthes Spine, K201605, EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

- *Secondary Predicate:* Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

- *Secondary Predicate:* Prosidyan Inc., K170306, FIBERGRAFT® BG Putty Bone Graft Substitute

12.2 Design and Technological Characteristics

The following tables provide a detailed comparison of the subject devices to the predicate devices, demonstrating that the subject devices are substantially equivalent to the predicate devices in terms of indications, manufacturing process, surgical approach, principles of operation, design and performance.

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12.2.1 SE Table - EIT Cellular Titanium® Cervical Cage

Table 1: Substantial Equivalence Table - EIT Cellular Titanium® Cervical Cage

Information	Subject Device	Primary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	DePuy Synthes	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **EIT Cellular Titanium® Cervical Cage**	**EIT Cellular Titanium Cervical Cage**, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage	-
510(k) Number	N/A	K201605	-
Product Code	ODP, MAX, MQV	MAX, ODP	(b)(4)
Classification	II	II	Yes – Both products are Class II
Intended Use	The EIT Cellular Titanium® Cervical Cages (CIF) are intended to restore intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1). In cases of segmental instability, the device is intended to be used with supplemental spinal fixation, applied anteriorly.	The EIT Cellular Titanium® Cervical Cages (CIF) are intended to restore intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1). In cases of segmental instability, the device is intended to be used with supplemental spinal fixation, applied anteriorly.	Yes – Intended use remains identical.
Indications for Use	The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT,	The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT,	Yes – The only difference in indications for use is that the subject device may be used with a bone void filler as cleared by FDA for use in intervertebral body fusion. This difference does not

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Information	Subject Device	Primary Predicate	Substantial Equivalence
	MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium® Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.	MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. EIT CellularTitanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.	raise any different or unexpected question of safety or efficacy as demonstrated by the clinical data provided within **Section 20** of this submission.
Technological Characteristics	The EIT Cellular Titanium® Cervical Cage is an implant made from a titanium alloy for the anterior stabilization of the cervical spinal column using an Anterior Cervical Discectomy and Fusion (ACDF) surgery. EIT Cellular Titanium Cervical Cages are offered in a variety of geometries and sizes to accommodate patient anatomy. The 3D Printed EIT Cellular Titanium® Cervical Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.	The EIT Cellular Titanium® Cervical Cage is an implant made from a titanium alloy for the anterior stabilization of the cervical spinal column using an Anterior Cervical Discectomy and Fusion (ACDF) surgery. EIT Cellular Titanium Cervical Cages are offered in a variety of geometries and sizes to accommodate patient anatomy. The 3D Printed EIT Cellular Titanium® Cervical Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.	Yes – The technological characteristics are identical.
Materials	Ti-6A1-4V ELI ASTM F3001	Ti-6A1-4V ELI ASTM F3001	Yes – The materials are identical.
Design	(b)(4)		Yes – The design of the devices are identical.

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Information	Subject Device	Primary Predicate	Substantial Equivalence
Size Range	(b)(4)		
Number of Implant Levels			
Sterility	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile and are sterilized by gamma irradiation.	Yes – The method of sterilization remains identical.
Biocompatibility	(b)(4)		
Packaging			
Shelf-Life			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

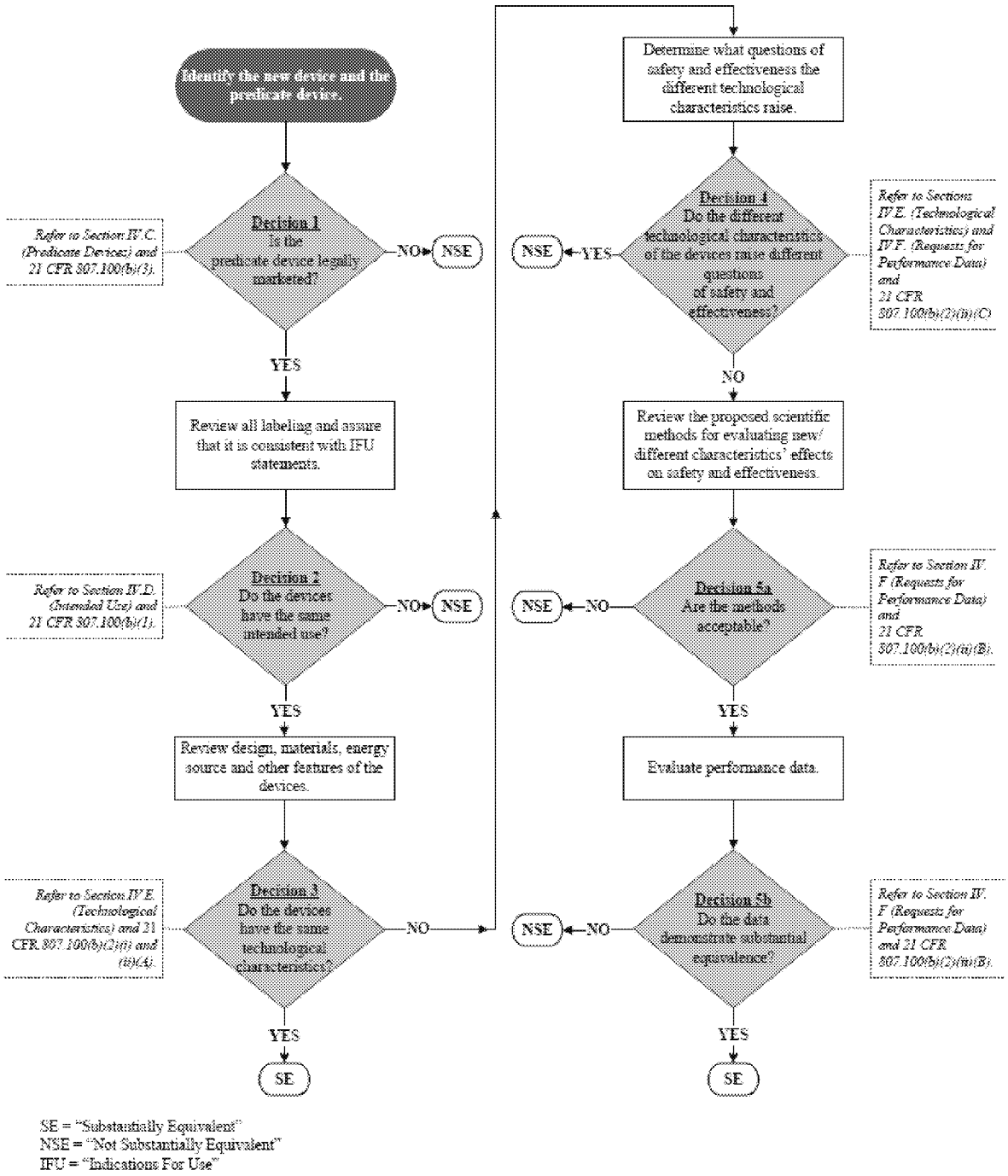

Figure 1: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K201605).

Decision 2: Do the devices have the same intended use?

Answer: Yes, the devices have the same intended use.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject device and primary predicate device have the same technological characteristics, including identical design, materials, principle of operation, and both devices are provided sterile (via gamma sterilization). The only difference in operative technique is that the subject device is indicated for use with an FDA-cleared bone void filler, whereas the primary predicate device is not. This difference has been demonstrated to not raise any different questions regarding the safety and efficacy, which is supported by clinical data.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, differences between the subject and predicate devices does not raise different questions of safety and effectiveness.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate device.

Overall, the EIT Cellular Titanium® Cervical Cage shares the following similarities to the primary predicate products:

- has identical intended use
- has similar indications
- has identical principles of operation
- has identical design
- has identical materials
- has identical biocompatibility, sterility, shelf-life, and packaging

Therefore, the EIT Cellular Titanium® Cervical Cage is found to be substantially equivalent to the predicate products.

12.2.2 SE Table - EIT Cellular Titanium® ALIF Cage

Table 2: Substantial Equivalence Table - EIT Cellular Titanium® ALIF Cage

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	DePuy Synthes	NuVasive Inc.	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **EIT Cellular Titanium® ALIF Cage**	EIT Cellular Titanium Cervical Cage, **EIT Cellular Titanium ALIF Cage**, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage	NuVasive Modulus ALIF System	-
510(k) Number	N/A	K201605	K203714	-
Product Code	ODP, MAX, MQV	MAX, ODP	MAX, MQV, OVD, PHM	Yes – Equivalent product codes
Classification	II	II	II	Yes – All products are Class II
Intended Use	The EIT Cellular Titanium® ALIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied anteriorly (e.g., using anterior plate system or anterior screw and rod system).	The EIT Cellular Titanium® ALIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied anteriorly (e.g., using anterior plate system or anterior screw and rod system).	The NuVasive Modulus ALIF System are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied anteriorly (e.g., using anterior plate system or anterior screw and rod system).	Yes – Intended use remains identical.
Indications for Use	The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a	The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition	The NuVasive Modulus ALIF System is indicated for spinal fusion procedures in skeletally mature patients. The Modulus ALIF System 10°-20° lordotic cages may be used as a standalone system. The Modulus ALIF System 25°-30° lordotic cages must be used with supplemental	Yes – The indications for use do not raise new concerns of safety or efficacy.

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.	requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.	internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The System is designed for use with autogenous bone graft, allogeneic bone graft comprised of cancellous and/ or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment. The NuVasive Modulus ALIF System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Modulus ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the Modulus ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.	

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Design	(b)(4)			
Materials	Ti-6A1-4V ELI ASTM F3001	Ti-6A1-4V ELI ASTM F3001	Ti-6Al-4V ELI conforming to ASTM F3001, ASTM F136 and ISO 5832-3	Yes – The materials are identical.
Size Range	(b)(4)			
Number of Implant Levels				

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Sterility	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile and are sterilized by gamma irradiation.	The implants may be provided as either sterile or non-sterile. Non-sterile implants are to be sterilized by the end user by steam autoclave.	Yes – The method of sterilization remains identical between the subject device and primary predicate device.
Biocompatibility	(b)(4)			
Packaging				
Shelf-Life				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

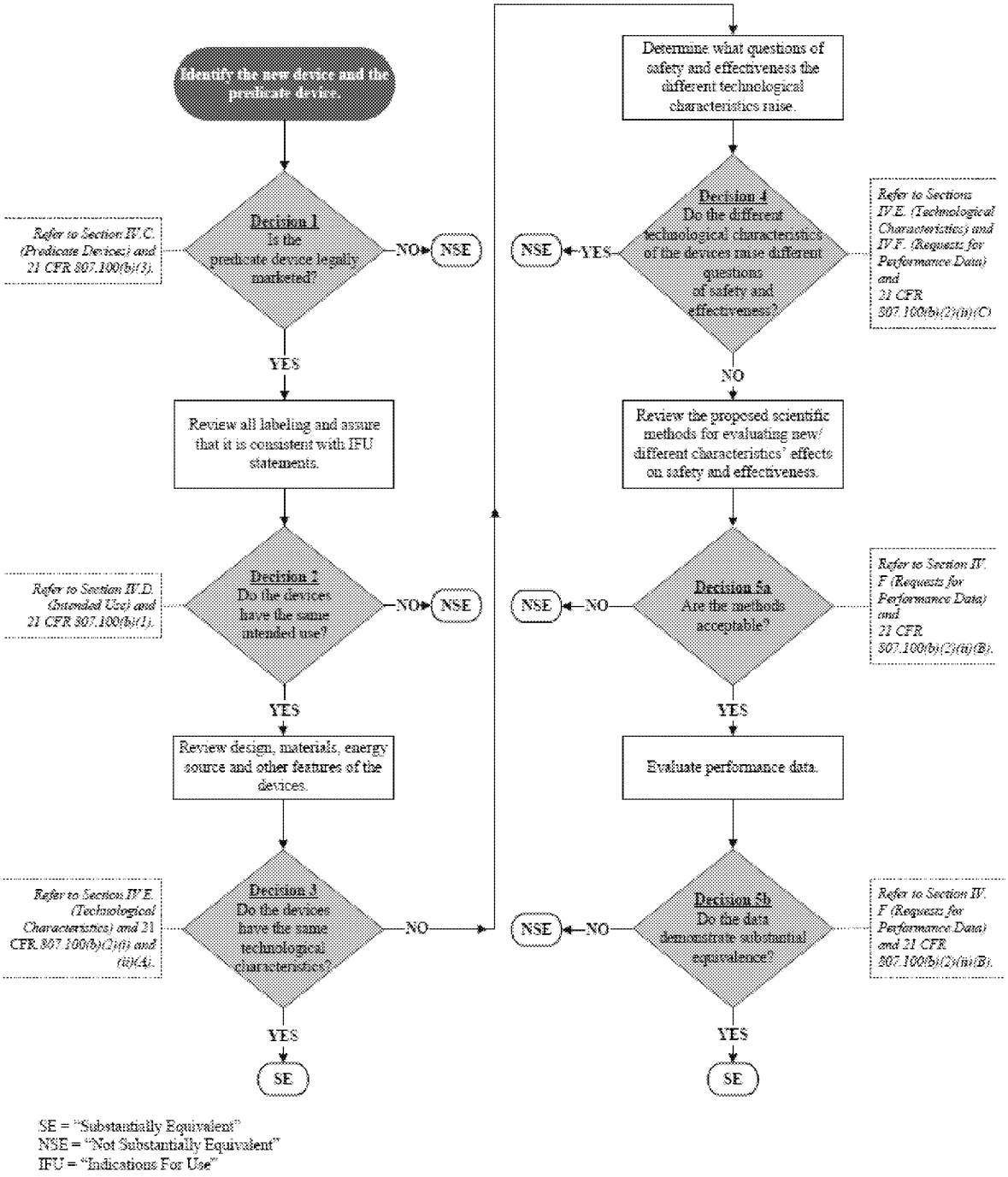

Figure 2: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K201605), and the secondary predicate is a legally marketed device (K203714).

Decision 2: Do the devices have the same intended use?

Answer: Yes, the devices have the same intended use.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject device and primary predicate device have the same technological characteristics, including identical design, materials, principle of operation, and both devices are provided sterile (via gamma sterilization). The only difference in operative technique between the subject device and the primary predicate is that the subject device is indicated for use with allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion. The subject device and secondary predicate device have equivalent technological characteristics, as both are available in a variety of heights, footprints, lordosis angles, and have the same principles of operation.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, differences between the subject and predicate devices does not raise different questions of safety and effectiveness.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable as they adequately evaluate the subject device per the device's indications for use.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate devices.

Overall, the EIT Cellular Titanium® ALIF Cage shares the following similarities to the predicate products:

- has identical intended use to the primary and secondary predicate
- has similar indications to the primary and secondary predicate
- has identical principles of operation as the primary predicate
- has identical design to the primary predicate
- has identical materials to the primary predicate
- has identical biocompatibility, sterility, shelf-life, and packaging to the primary predicate

Therefore, the EIT Cellular Titanium® ALIF Cage is found to be substantially equivalent to the predicate products.

12.2.3 SE Table - EIT Cellular Titanium® TLIF Cage

Table 3: Substantial Equivalence Table - EIT Cellular Titanium® TLIF Cage

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	DePuy Synthes	NuVasive Inc.	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **EIT Cellular Titanium® TLIF Cage**	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, **EIT Cellular Titanium TLIF Cage**, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage	NuVasive Modulus TLIF System	-
510(k) Number	N/A	K201605	K203714	-
Product Code	ODP, MAX, MQV	MAX, ODP	MAX, MQV, OVD, PHM	Yes – Equivalent product codes
Classification	II	II	II	Yes – All products are Class II
Intended Use	The EIT Cellular Titanium® TLIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws) or transforaminally.	The EIT Cellular Titanium® TLIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws) or transforaminally.	The NuVasive Modulus TLIF System is used to restore intervertebral height and to facilitate intervertebral body fusion in the thoracolumbar spine (T1 to T12, the thoracolumbar junction (T12-L1), and the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation.	Yes – The subject device and primary predicate have identical intended uses. The subject device and secondary predicate device have similar intended uses; however, while both devices are intended for use at the L2-S1 levels, only the secondary predicate is intended for use at the

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
				T1-T12 and T12-L1 levels.
Indications for Use	The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.	The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.	The NuVasive Modulus TLIF Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment. The NuVasive Modulus TLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use in the lumbar spine from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Modulus TLIF Interbody System can also be used as an adjunct to fusion in patients	Yes – The indications for use do not raise new concerns of safety or efficacy.

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
			diagnosed with multilevel degenerative scoliosis and sagittal deformity.	
Design	(b)(4)			
Materials	Ti-6A1-4V ELI ASTM F3001	Ti-6A1-4V ELI ASTM F3001	Ti-6Al-4V ELI conforming to ASTM F3001, ASTM F136 and ISO 5832-3	Yes – The materials are identical.
Size Range	(b)(4)			
Number of Implant Levels				
Sterility	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile.	Yes – The method of sterilization remains identical for the subject device and primary predicate device.
Biocompatibility	(b)(4)			

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	(b)(4)			
Packaging				
Shelf-Life				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

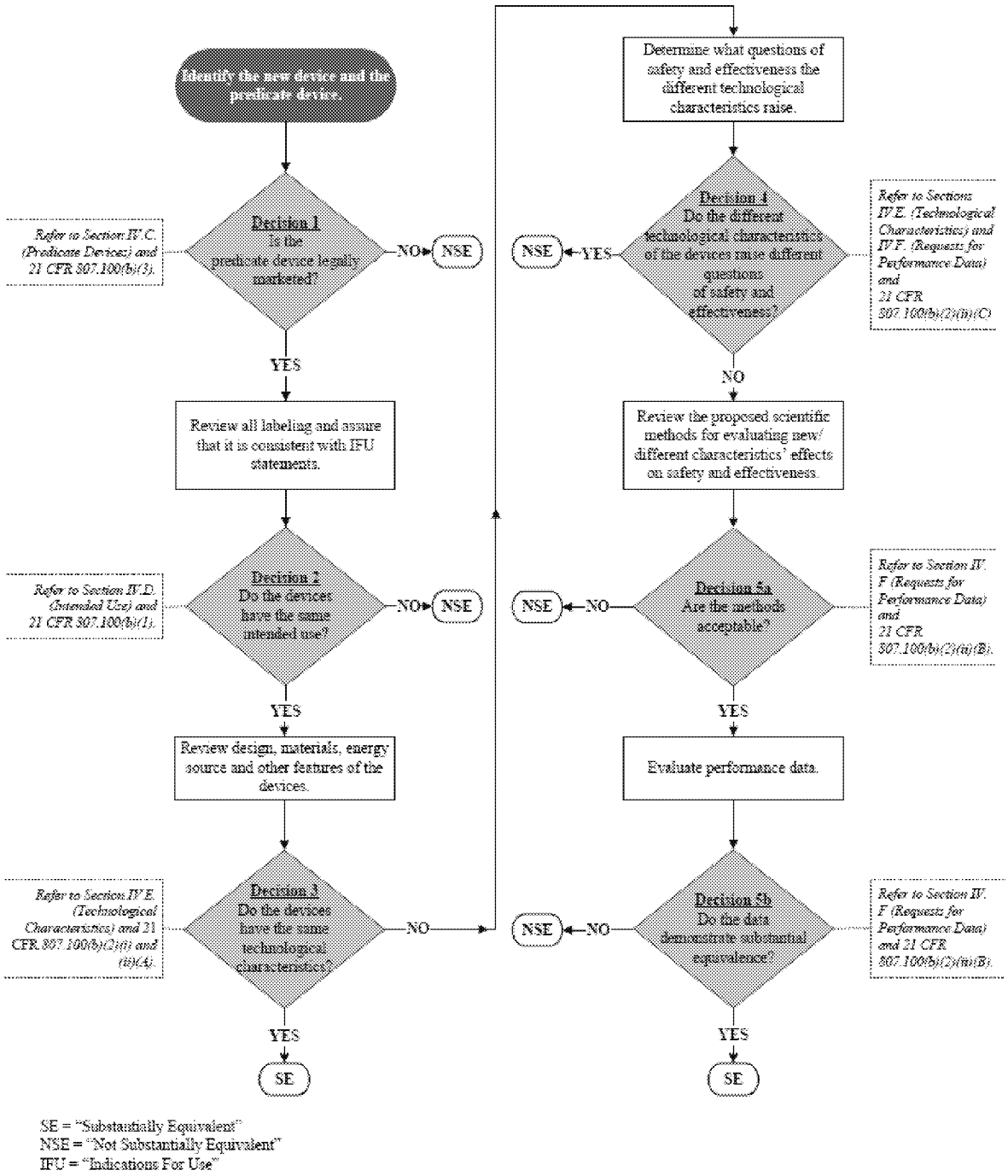

Figure 3: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K201605), and the secondary predicate is a legally marketed device (K203714).

Decision 2: Do the devices have the same intended use?

Answer: Yes, the subject device and the predicate devices have the same intended use.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject device and primary predicate device have the same technological characteristics, including identical design, materials, principle of operation, and both devices are provided sterile (via gamma sterilization). The only difference in operative technique between the subject device and the primary predicate is that the subject device is indicated for use with allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion. The subject device and secondary predicate device have equivalent technological characteristics, including design, materials, and principles of operation.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, differences between the subject and predicate devices does not raise different questions of safety and effectiveness.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate device.

Overall, the EIT Cellular Titanium® TLIF Cage shares the following similarities to the predicate products:

- has similar intended use to the primary and secondary predicates
- has similar indications to the primary and secondary predicates
- has identical principles of operation
- has identical design to the primary predicate
- has identical materials to the primary predicate
- has identical biocompatibility, sterility, shelf-life, and packaging to the primary predicate

Therefore, the EIT Cellular Titanium® TLIF Cage is found to be substantially equivalent to the predicate products.

12.2.4 SE Table - EIT Cellular Titanium® LLIF Cage

Table 4: Substantial Equivalence Table - EIT Cellular Titanium® LLIF Cage

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	DePuy Synthes	NuVasive Inc.	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **EIT Cellular Titanium® LLIF Cage**	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, **EIT Cellular Titanium LLIF Cage**, EIT Cellular Titanium T/PLIF Cage	NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty - **NuVasive Brigade Lateral System**	-
510(k) Number	N/A	K201605	K203714	-
Product Code	ODP, MAX, MQV	MAX, ODP	MAX, MQV, OVD, PHM	Yes – Equivalent product codes
Classification	II	II	II	Yes – All products are Class II
Intended Use	The EIT Cellular Titanium® Lumbar Cage LLIF is intended to be used from L2-S1 in patients with DDD and up to Grade I spondylolisthesis or retrolisthesis at one or two contiguous levels. The device is intended to be used alongside supplemental spinal fixation, either applied anteriorly or posteriorly (e.g., using posterior pedicle screws).	The EIT Cellular Titanium® Lumbar Cage LLIF is intended to be used from L2-S1 in patients with DDD and up to Grade I spondylolisthesis or retrolisthesis at one or two contiguous levels. The device is intended to be used alongside supplemental spinal fixation, either applied anteriorly or posteriorly (e.g., using posterior pedicle screws).	The NuVasive Brigade Lateral System is intended to be used from L2-S1 in patients with DDD or degenerative spondylolisthesis at one or two adjacent levels. The device may also be used as an adjunct to fusion in patients diagnoses with multilevel degenerative scoliosis and sagittal deformity. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by FDA for use in the lumbar spine.	(b)(4)

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
				(b)(4)
Indications for Use	The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.	The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.	The Brigade Lateral System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Lateral System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous bone graft, allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of nonoperative treatment. The Brigade Lateral System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade Lateral System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.	Yes – The indications for use do not raise new concerns of safety or efficacy.

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Design	(b)(4)			
Materials	Ti-6A1-4V ELI ASTM F3001	Ti-6A1-4V ELI ASTM F3001	PEEK-OPTIMA LT-1 (Polyether-etherketone) conforming to ASTM F2026 and Ti-6Al-4V ELI conforming to ASTM F136/ ISO 5832-3 and fixation screw manufactured from Ti-6Al-4V conforming to ASTM F1472.	(b)(4)

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
				(b)(4)
Size Range	(b)(4)			
Number of Implant Levels				
Sterility	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile and are sterilized by gamma irradiation.	The implants may be provided as either sterile or non-sterile. Non-sterile implants are to be sterilized by the end user by steam autoclave.	Yes – The method of sterilization remains identical between the subject device and

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
				primary predicate device.
Biocompatibility	(b)(4)			
Packaging				
Shelf-Life				

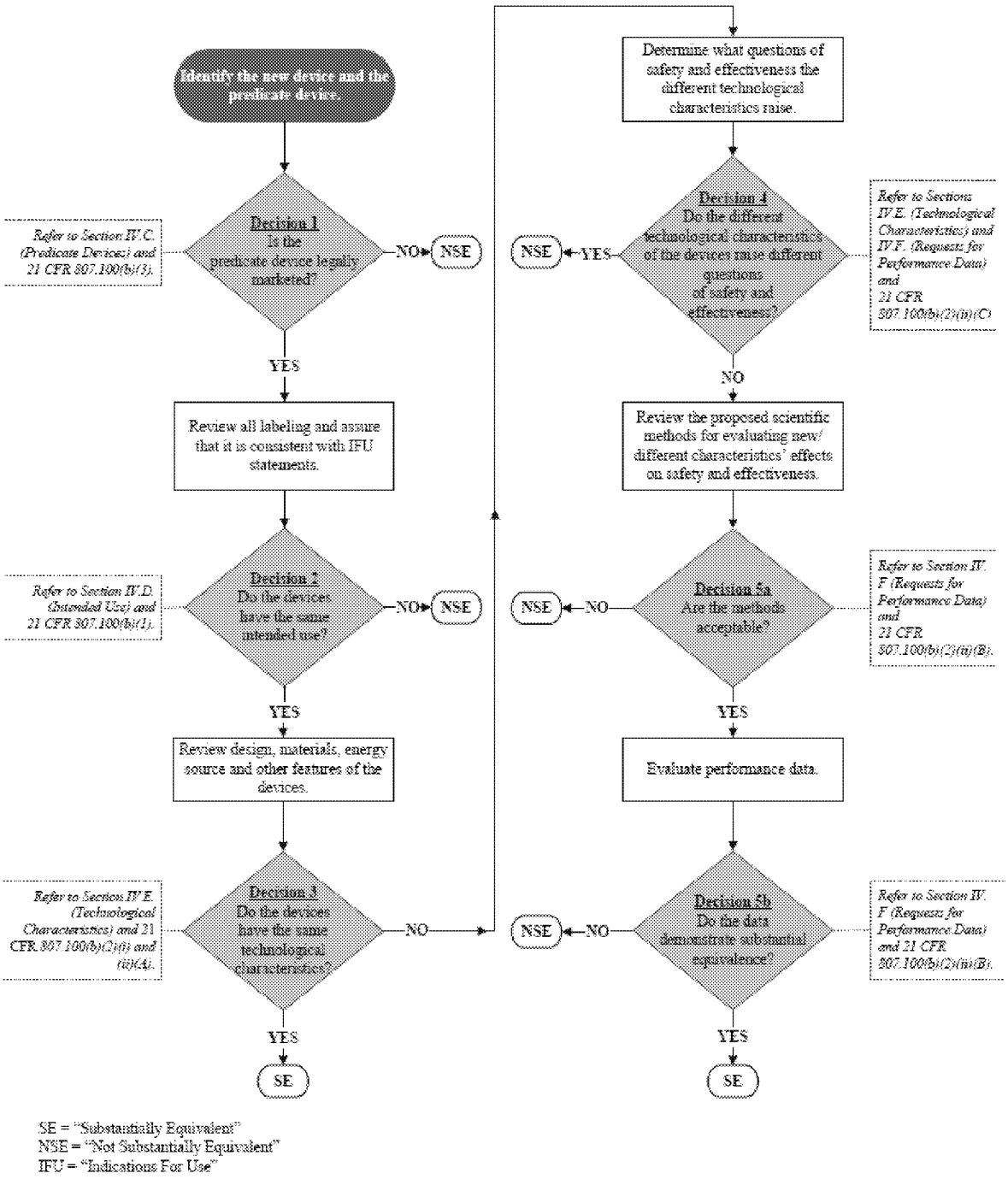

Figure 4: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K201605), and the secondary predicate is a legally marketed device (K203714).

Decision 2: Do the devices have the same intended use?

Answer: Yes, the subject device and predicate devices have the same intended use.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject device and primary predicate device have the same technological characteristics, including identical design, materials, principle of operation, and both devices are provided sterile (via gamma sterilization). The only difference between the subject device and primary predicate is that the subject device is indicated for use with an FDA-cleared bone void filler, whereas the primary predicate device is not. This difference has been demonstrated to not raise any different questions regarding the safety and efficacy, which is supported by clinical data. The subject device and secondary predicate device have equivalent technological characteristics, as both are available in a variety of heights, footprints, and lordosis angles. Additionally, the cage component of the secondary predicate is manufactured from PEEK-OPTIMA LT-1, which is different from the subject device.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, differences between the subject and predicate devices do not raise different questions of safety and effectiveness. With regards to the difference in materials used in the subject device and secondary predicate, this difference is not expected to result in any clinical differences as both PEEK and Ti6Al4V ELI are both well-established materials with demonstrated successful clinical use in interbody cage devices.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate devices.

Overall, the EIT Cellular Titanium® LLIF Cage shares the following similarities to the predicate products:

- has similar intended use to the primary and secondary predicates
- has similar indications to the primary and secondary predicates
- has identical principles of operation to the primary predicate
- has identical design to the primary predicate
- has identical materials to the primary predicate
- has identical biocompatibility, sterility, shelf-life, and packaging to the primary predicate

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Therefore, the EIT Cellular Titanium® LLIF Cage is found to be substantially equivalent to the predicate products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

12.2.5 SE Table - EIT Cellular Titanium® T/PLIF Cage

Table 5: Substantial Equivalence Table - EIT Cellular Titanium® T/PLIF Cage

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	DePuy Synthes	NuVasive Inc.	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **EIT Cellular Titanium® T/PLIF Cage**	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT **Cellular Titanium T/PLIF Cage**	NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty – **Coalesce Thoracolumbar Interbody Fusion System**	-
510(k) Number	N/A	K201605	K203714	-
Product Code	ODP, MAX, MQV	MAX, ODP	MAX, MQV, OVD, PHM	Yes – Equivalent product codes
Classification	II	II	II	Yes – All products are Class II
Intended Use	The EIT Cellular Titanium® T/PLIF Cages are intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws).	The EIT Cellular Titanium® T/PLIF Cages are intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws).	The Coalesce Thoracolumbar Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain).	Yes – The subject device and primary predicate have identical intended uses. The subject device and secondary predicate have similar intended uses.
Indications for Use	The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated	The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone	The Coalesce Thoracolumbar Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with	Yes – The indications for use do not raise

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.	graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.	autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment. The Coalesce Thoracolumbar Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Coalesce Thoracolumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.	new concerns of safety or efficacy.
Design	(b)(4)			

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	(b)(4)			
Materials	Ti-6A1-4V ELI ASTM F3001	Ti-6A1-4V ELI ASTM F3001	PEEK	Yes – The materials of the subject device and primary predicate device are identical.
Size Range	(b)(4)			
Number of Implant Levels				
Sterility	The cages are provided sterile and are sterilized by gamma irradiation.	The cages are provided sterile and are sterilized by gamma irradiation.	Not Available	Yes – The method of sterilization used for the subject device and primary predicate device remains identical.
Biocompatibility	(b)(4)			
Packaging				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Shelf-Life	(b)(4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

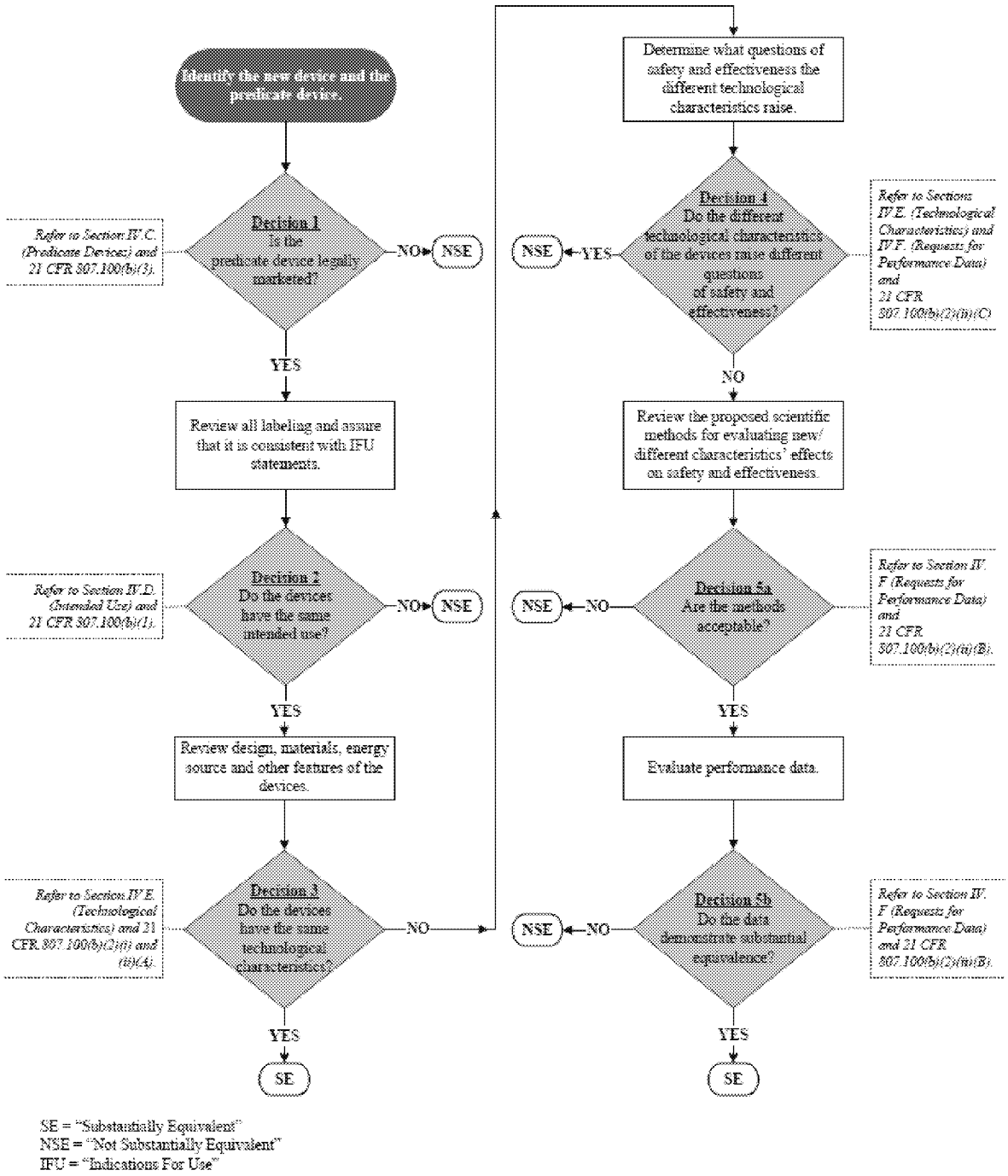

Figure 5: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K201605), and the secondary predicate is a legally marketed device (K203714).

Decision 2: Do the devices have the same intended use?

Answer: Yes, the subject device and the predicate devices have the same intended use.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject device and primary predicate device have the same technological characteristics, including identical design, materials, principle of operation, and both devices are provided sterile (via gamma sterilization). The only difference in operative technique between the subject device and the primary predicate is that the subject device is indicated for use with allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion. The subject device and secondary predicate device have equivalent technological characteristics, as both are available in a variety of heights, footprints, lordosis angles, and have the same principles of operation.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, differences between the subject and predicate devices does not raise different questions of safety and effectiveness.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate device.

Overall, the EIT Cellular Titanium® T/PLIF Cage shares the following similarities to the predicate products:

- has identical intended use to the primary predicate
- has similar indications to the primary and secondary predicates
- has identical principles of operation to the primary and secondary predicates
- has identical design to the primary predicate
- has identical materials to the primary predicate
- has identical biocompatibility, sterility, shelf-life, and packaging to the primary predicate

Therefore, the EIT Cellular Titanium® T/PLIF Cage is found to be substantially equivalent to the predicate products.

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12.2.6 SE Table - FIBERGRAFT® BG Putty Bone Graft Substitute

Table 6: Substantial Equivalence Table - FIBERGRAFT® BG Putty Bone Graft Substitute

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Manufacturer	DePuy Synthes	Prosidyan Inc.	Nuvasive Inc.	-
Trade Name	EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty - **FIBERGRAFT® BG Putty Bone**	FIBERGRAFT® BG Putty Bone Graft Substitute	Nuvasive Attrax Putty	-
510(k) Number	N/A	K170306	K203714	-
Product Code	ODP, MAX, MQV	MQV	MAX, MQV, OVD, PHM	Yes – Same product code for the bone void filler component of each system (MQV)
Classification	II	II	II	Yes – All products are Class II
Intended Use	Bone void filler for orthopedic	Bone void filler for orthopedic	Bone void filler for orthopedic	Yes – Identical intended use
Indications for Use	FIBERGRAFT® BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT® BG Putty must be used with autograft in the posterolateral spine.	FIBERGRAFT® BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT® BG Putty must be used with autograft in the posterolateral spine. FIBERGRAFT® BG Putty is not indicated for use in load-bearing applications; therefore, standard internal	Attrax Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, and pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bone structure. NuVasive Attrax Putty resorbs and is replaced with bone during the healing process. NuVasive Attrax Putty may be used in combination with autogenous bone in the posterolateral spine and pelvis. When used in intervertebral body fusion procedures, NuVasive Attrax Putty must be used on its own with an intervertebral body fusion	Yes – The indications for use do not raise new concerns of safety or efficacy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	When used in intervertebral body fusion procedures, FIBERGRAFT® BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.	or external stabilization techniques must be followed to obtain rigid stabilization.	device cleared by FDA for use with a bone void filler.	
Primary Component	(b)(4)			
Composition				
Carrier Composition				
Interconnected pores / porosity				
Pore Structure				
Particulate Diameter				
Osteoconductive				
Bioactive				
Sterility				

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Information	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Yes – All products are biocompatible.
Dosage Form (sizes)	(b)(4)			
Packaging				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

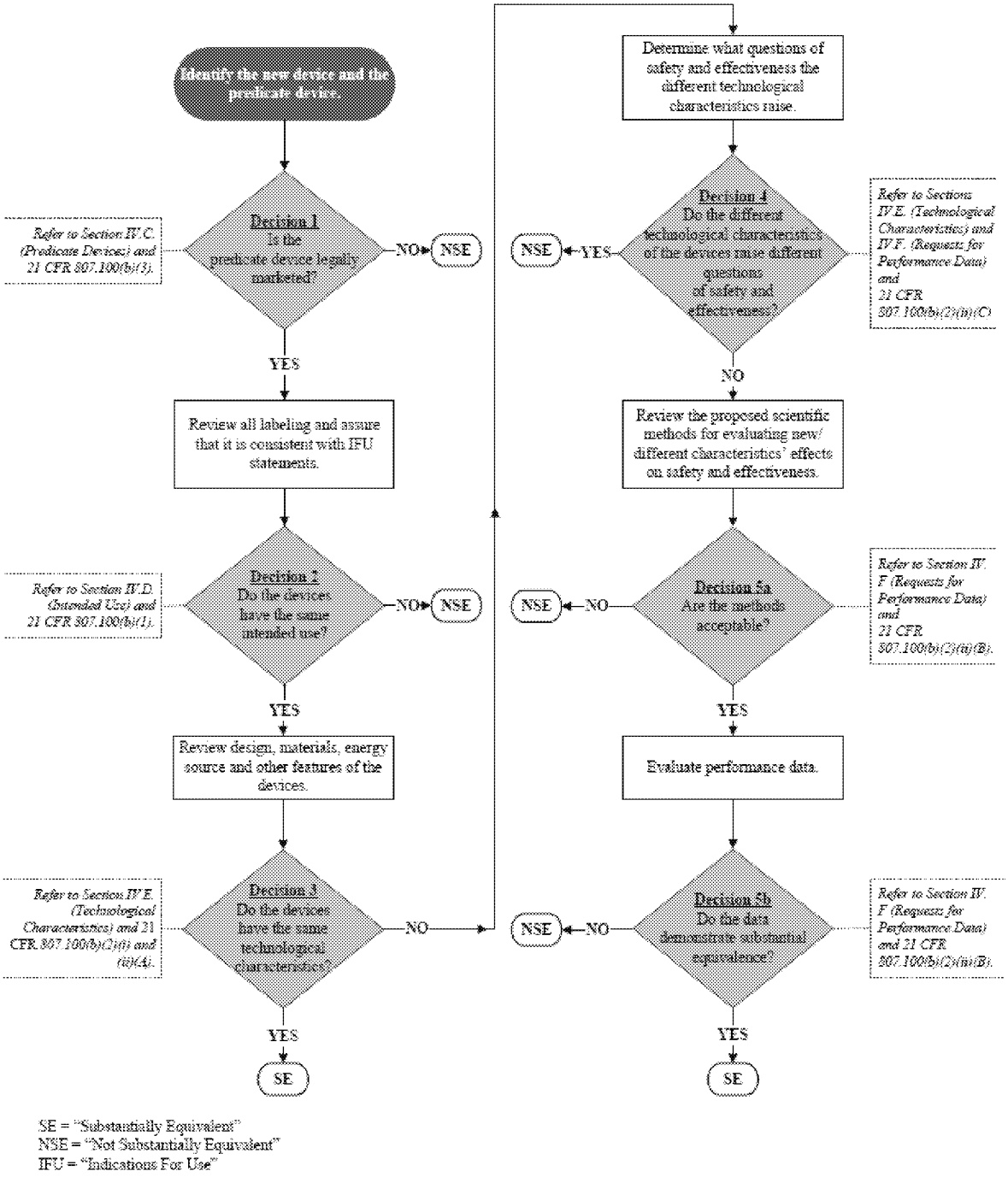

Figure 6: Equivalence Flow Chart and Accompanying Relevant Comparison Questions

Decision 1: Are the predicate devices legally marketed?

Answer: Yes, the primary predicate is a legally marketed device (K170306), and the secondary predicate is a legally marketed device (K203714).

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Decision 2: Do the devices have the same intended use?

Answer: Yes, the subject device has the same intended use as the predicate devices. Any differences in indications do not raise any questions of safety and efficacy as demonstrated by the clinical data in **Section 20**.

Decision 3: Do the devices have the same technological characteristics?

Answer: Yes, the subject and primary predicate devices have identical technological characteristics.

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Answer: No, there are no differences in technological characteristics between the subject device and primary predicate device.

Decision 5a: Are the methods acceptable?

Answer: Yes, the methods used to determine substantial equivalence are acceptable.

Decision 5b: Do the devices demonstrate substantial equivalence?

Answer: Yes, the subject device is substantially equivalent to the predicate device.

Overall, the FIBERGRAFT® BG Putty shares the following similarities to the predicate products:

- has identical intended use
- has similar indications
- has identical principles of operation
- has identical design
- has identical materials
- has identical sterility, and packaging
- has similar biocompatibility and shelf-life

Therefore, the FIBERGRAFT® BG Putty is found to be substantially equivalent to the predicate products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUMMARY

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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20. PERFORMANCE TESTING – CLINICAL

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

[cid:image003.png@01D8D8CA.BAF60B70]<http://secure-web.cisco.com/1bPmvkOxFf2-_xdUMz6sEOqsjsjOpWdQlnp_bnMk6o6wJXfrD5bkfvfxns-0ZtPYhpt9aefTohG2zqVgsOd3GImGRCp3gFTzLTUTx9xBzpaij6slO6y_UYkLYlOIFb72-V3KxEzpX82h1Z9nPBihj2MesAsxVKj8dXfN1OCD4Qz3ZkS2u_9Id57fSQ_EjoqEqCJsedIGFejg8Yt_oS4wkJw/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1_ryQ27CLoxSYT-XGkBnYJiZSV1S7GLA6Fa0alIBKC8yidOnM3vh1QFlzZCJsBzlVYuqF3zb9M7irWNR0Aq5XrXP3wCpoZTvV3ZpRIkupx-213AUY3VlqKqvcIw4kOzUTkJrDM8PTyyKyXyjB1_IE7zEgx6v8lfN3LOtSs4Fe80vKoazE7Q-ZLufsFmKLtQbeeh0gYUdQBD-k5srvUFLNSw/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1bPmvkOxFf2-_xdUMz6sEOqsjsjOpWdQlnp_bnMk6o6wJXfrD5bkfvfxns-0ZtPYhpt9aefTohG2zqVgsOd3GImGRCp3gFTzLTUTx9xBzpaij6slO6y_UYkLYlOIFb72-V3KxEzpX82h1Z9nPBihj2MesAsxVKj8dXfN1OCD4Qz3ZkS2u_9Id57fSQ_EjoqEqCJsedIGFejg8Yt_oS4wkJw/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8D8CA.BAF60B70]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update (b)(4) are attached to this email for your review.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1_ryQ27CLoxSYT-XGkBnYJiZSV1S7GLA6Fa0alIBKC8yidOnM3vh1QFlzZCJsBzlVYuqF3zb9M7irWNR0Aq5XrXP3wCpoZTvV3ZpRIkupx-213AUY3VlqKqvcIw4kOzUTkJrDM8PTyyKyXyjB1_IE7zEgx6v8lfN3LOtSs4Fe80vKoazE7Q-ZLufsFmKLtQbeeh0gYUdQBD-k5srvUFLNSw/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dMtpztD4aXZhAUtxppCDzG94ER1vwlRI1kw2hLVWsAY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. The responses

(b)(4)

Thanks,

Justin

[cid:image009.png@01D8D8CA.BAF60B70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

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sender immediately by telephone at 202-552-5800 or by reply email and delete this message immediately. Thank you.

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) (also attached). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image018.png@01D8D8CA.BAF60B70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981789017%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=myIoqRnOoz5Yji4C107jv0gtyVhsKh51adDd%2FFcKNJA%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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[cid:image021.jpg@01D8D8CA.BAF60B70]
<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2FUS_FDA&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981945248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=NpzOfH6LquQsV1ZZAOe5cZBVaF4rqu46TeQYOJQoqtw%3D&reserved=0> [cid:image022.jpg@01D8D8CA.BAF60B70]
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THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution, copying, or other action based on the content of this communication is NOT AUTHORIZED. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

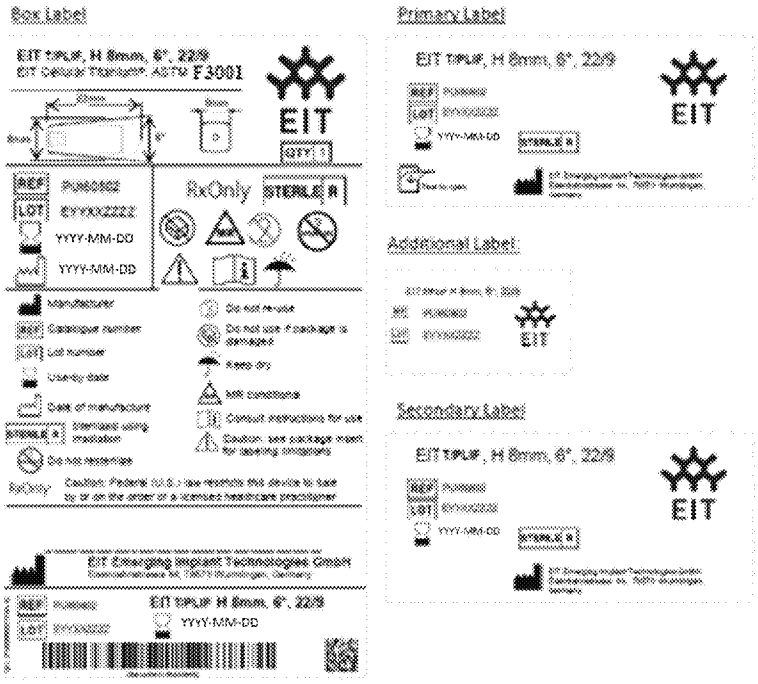
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://secure-web.cisco.com/13VB9VDRZIfpKiugo1d6lV9wFXVF6N4eyRVRxz5BuExi-gfZCuQ4isZzMQr_4OaG3EfxCpFSEF0v-fe5kSjpOL8x88AtmvVW5NGkgLm3rHgX9r2_JtdhVGzoM0fI7DZpI4FvRr91agw15JlPfcVcbS2cR_M6WrF7lABHXukYBoiXVSJJIhdWPxIbrVK8ZyJIF4KPHU41JjLTkqIgOaeFd-EJGfBC5u6FAWY5R8D6F3MU/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981945248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=bxvb9czoi7QyID6M58pZ1BnzXK4xpHs%2FbUtq5H%2BoXSM%3D&reserved=0>.

13. Proposed Labeling:

The labeling for the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty are included in the sections below. The Instructions for Use (IFU) for the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty can be found within **Appendix C**. The Surgical Technique Guide (STG) for the EIT Cellular Titanium® Cages can be found within **Appendix D**. The princples of operation for the FIBERGRAFT® BG Putty are included within the IFU and can be found in **Appendix C**.

13.1 Proposed Labels - EIT Cellular Titanium® Cages

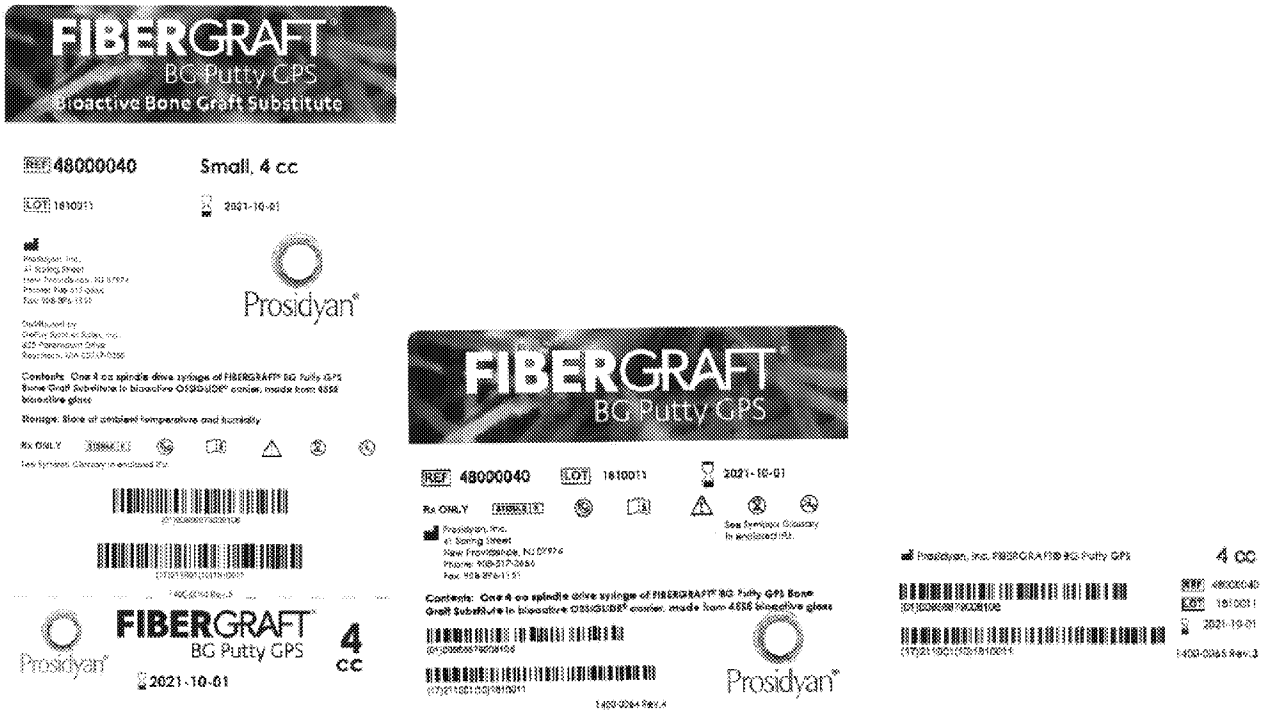
A representative sample of a package label for the EIT Cellular Titanium® T/PLIF Cage is shown below. Labels for each catalog number will differ by part number, size, etc. but will follow this format. Variable fields are shown in yellow. These are unchanged from the previously cleared products.



13.2 Proposed Labels - FIBERGRAFT® BG Putty

13.2.1 FIBERGRAFT® BG Putty Shelf-Box Label, Pouch Label, Patient Chart Labels

13.2.2 FIBERGRAFT® BG Putty GPS Shelf-Box Label, Pouch Label, Patient Chart Labels



13.2.3 FIBERGRAFT® BG Putty GPS Cannula Shelf-Box Label, Pouch Label, Patient Chart Labels

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Response to Interactive Questions

(b)(4)

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(b)(4)

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222276 Date Received by DCC: Jul 29, 2022

Lead Reviewer: Jennifer Houck, MS

Center: CDRH Office: OHT 6 Division: DHT6C

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions **Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)**	**Yes**	**No**	**N/A**
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐		☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*		☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.		☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.		☒	☐
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (https://www.fda.gov/media/86323/download).*	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☒		☐	☐	
a) Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☒	☐	☐		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☒		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐		
i) For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that is was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812.	☒	☐	☐		
ii) For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.	☐	☐	☒		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☐	☐	☒		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☐	☒		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☒		
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual)	☒	☐		☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling).	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☐	☒		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☐	☐	☒		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☐	☒		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☒		☐	☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☐	☒		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does contain software/firmware					
☒ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☐	☐	☒	☐	
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☒		☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☐	☐	☒		
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
40) If literature is referenced in the submission, submission includes:			☐		
a) Legible reprints or a summary of each article.	☒	☐			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☒	☐			
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Jennifer Houck -S Digitally signed by Jennifer Houck -S Date: 2022.08.10 10:13:49 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

From: Longus, Monique * [Monique.Longus@fda.hhs.gov]
Sent: 7/29/2022 8:23:03 PM
To: jeggleton@mcra.com
Subject: K222276 Acknowledgement Notification
Attachments: K222276 Acknowledgment Letter.pdf

Corrected acknowledgement notification

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U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

7/29/2022

Justin Eggleton, Vice President, Spine Regulatory Affairs
MCRA LLC
803 7th St NW
Washington, DC 20001
UNITED STATES

Dear Justin Eggleton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K222276
Received: 07/29/2022
Applicant: DePuy Spine
Device: EIT Cellular Titanium Cages; FIBERGRAFT BG Putty

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

B. Date Prepared

September 28, 2022

C. Device Name - CONDUIT™ Cages

Trade/Proprietary Name: CONDUIT™ Cages

Common/Usual Name: Intervertebral body fusion device

Regulatory Class: Class II per 21 CFR §888.3080

Review Panel: Orthopedic

Product Codes: ODP, MAX

D. Device Name - FIBERGRAFT™ BG Putty

Trade/Proprietary Name: FIBERGRAFT™ BG Putty

Common/Usual Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II per 21 CFR §888.3045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Review Panel: Orthopedic

Product Codes: MQV

E. Predicate Device Names

Primary Predicate: DePuy Synthes Spine, K201605, EIT Cellular Cervical Cage, EIT Cellular ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

Additional Predicate: Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Additional Predicate: Prosidyan Inc., K170306, FIBERGRAFT™ BG Putty Bone Graft Substitute

F. Device Description

The CONDUIT™ Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The CONDUIT™ Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous, or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed CONDUIT™ Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The purpose of this submission is to expand the indications for use of the CONDUIT™ Cages to include its use with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bonegraft.

G. Indications for Use

CONDUIT™ Cervical Cage

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

CONDUIT™ ALIF Cage

The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

CONDUIT™ TLIF Cage

The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and

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radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

CONDUIT™ LLIF Cage

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano- scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONDUIT™ T/PLIF Cage

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

FIBERGRAFT™ BG Putty

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty is not indicated for use in load-bearing applications; therefore, standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ BG Putty GPS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ GPS Cannula

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The purpose of this Traditional 510(k) is to expand the indications for use of the CONDUIT™ Cages to include its used with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The subject device is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. There are no differences in technological characteristics that will raise new concerns of safety or performance.

I. Materials

The CONDUIT™ Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001. The BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicate. The materials and manufacturing process for the CONDUIT™ subject devices are identical to that of the predicate device. Similarly, the materials and composition of the BG Putty device are identical to that of the predicate device and the manufacturing process remains substantially the same as that of the predicate. It is important to note that the manufacturing location of BG Putty was moved from Steris to Prosidyan (now DePuy Synthes), however the process has not changed.

J. Performance Data

The performance of the CONDUIT™ Cervical and Lumbar Cages and the FIBERGRAFT™ BG Putty have been assessed individually within their respective submissions (K201605, and K170306). Clinical data has been utilized to demonstrate the performance and safety of the expanded indications for use, which includes the use of the CONDUIT™ Cages with FIBERGRAFT™ BG Putty. The clinical data includes radiographic and clinical outcomes from a retrospective study and two investigator-initiated studies. The data provided includes 178 subjects and was collected from multiple sites across the United States (CA, TX, FL) to capture a variety of populations with diverse gender and racial/ethnic backgrounds that is representative of the intended users of the subject devices. The results of the data support the performance of the subject devices in intervertebral body fusion based on fusion and adverse event rates. Additional rationales were provided to justify the expanded indications based upon the clinical data results.

K. Conclusion

Based on the body of data presented throughout the submission, it has been determined that the subject devices are substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, and performance data.

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August 10, 2022</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K222276, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Jennifer Houck. The file is being reviewed in Office of Health Technology 6, Division of Health Technology 6 C. The first line supervisor is the Assistant Director, Restorative, Repair, Trauma and Fracture Fixation Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

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6. TRUTHFUL AND ACCURATE STATEMENT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President, Global Regulatory Affairs of DePuy Synthes Spine, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

July 29, 2022

Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

11. DEVICE DESCRIPTION

The purpose of this submission is to expand the indications for use of the EIT Cellular Titanium® Cages to include its use with FIBERGRAFT® BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The following sections include a description of the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty. It is important to note that no changes to the FIBERGRAFT® BG Putty or the EIT Cellular Titanium® Cages have been made since their most recent clearances.

11.1 System Description - EIT Cellular Titanium® Cages

The EIT Cellular Titanium® Cages are identical to those cleared in K201605. The purpose of this submission is to expand the indications for use of the EIT Cellular Titanium® Cages to include its use with FIBERGRAFT® BG Putty. Engineering Drawings for the EIT Cellular Titanium® Cages can be found in prior submission.

The EIT Cellular Titanium® Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g., using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The EIT Cellular Titanium® Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed EIT Cellular Titanium® Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

11.1.1 EIT Cellular Titanium® Cervical Cages

The EIT Cellular Titanium® Cervical Cages (CIF) are intended to restore intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1). In cases of segmental instability, the device is intended to be used with supplemental spinal fixation, applied anteriorly (e.g., using anterior plate system or anterior screw and rod system). Please refer to the complete indications for use statement presented in the FDA Form 3881.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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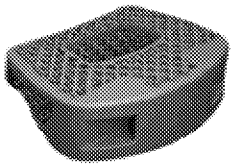

Figure 1: EIT Cellular Titanium® Cervical Cage

The size description of the EIT Cellular Titanium® Cervical Cages is presented below (**Table 1**).

(b)(4)

11.1.2 EIT Cellular Titanium® ALIF Cages

The EIT Cellular Titanium® ALIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied anteriorly (e.g., using anterior plate system or anterior screw and rod system). Please refer to the complete indications for use statement presented in the FDA Form 3881.

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Figure 2: EIT Cellular Titanium® ALIF Cage

The size description of the EIT Cellular Titanium® ALIF Cages is presented below (**Table 2**).

Table 2: Implant Sizing Overview for ALIF

(b)(4)

The materials used, manufacturing processes and instruments with the EIT Cellular Titanium® ALIF Cages remain unchanged from the predicate device clearance (K201605). The instrument codes which were also cleared in K201605.

11.1.3 EIT Cellular Titanium® LLIF Cages

The EIT Cellular Titanium® LLIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used alongside supplemental spinal fixation, applied anteriorly or posteriorly (e.g., using posterior pedicle screws). Please refer to the complete indications for use statement presented in the FDA Form 3881.

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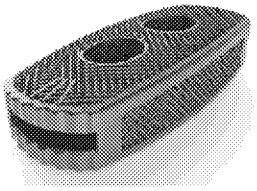

Figure 3: LLIF Cages

The size description of the EIT Cellular Titanium® LLIF Cages is presented in **Table 3**.

Table 3: Implant Sizing Overview for LLIF

(b)(4)

The materials used, manufacturing processes and instruments with the EIT Cellular Titanium® LLIF Cages remain unchanged from the predicate device clearance (K201605). The instrument codes which were also cleared in K201605.

11.1.4 EIT Cellular Titanium® TLIF Cages

The EIT Cellular Titanium® TLIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws) or transforaminally. Please refer to the complete indications for use statement presented in the FDA Form 3881.

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Figure 4: EIT Cellular Titanium® TLIF Cage

The size description of the EIT Cellular Titanium® TLIF Cages is presented below (**Table 4**).

(b)(4)

The materials used, manufacturing processes and instruments used with the EIT Cellular Titanium® TLIF Cages remain unchanged from the predicate device clearance (K201605). The instrument codes which were also cleared in K201605.

11.1.5 EIT Cellular Titanium® T/PLIF Cages

The EIT Cellular Titanium® T/PLIF Cages are used to restore intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1). The devices are intended to be used with supplemental spinal fixation, applied posteriorly (e.g., using posterior pedicle screws). Please refer to the complete indications for use statement presented in the FDA Form 3881.

Figure 5: EIT Cellular Titanium® T/PLIF Cage

Table 5: Implant Sizing Overview for T/PLIF

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000048

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The materials used, manufacturing process and instruments used with the T/PLIF cage remain unchanged from the predicate device clearance (K201605). The instrument codes which were cleared in K201605.

11.1.6 EIT Cellular Titanium® Cage Instruments

The instruments used to implant the EIT Cellular Titanium® Cages are identical to the instruments previously cleared in K201605.

11.2 System Description - FIBERGRAFT® BG Putty Bone Graft Substitute

FIBERGRAFT® BG Putty Bone Graft Substitute's intended use/indications for use, technological characteristics, and principles of operation are described below. It is important to note that there have been no changes in the putty's technological characteristics or principles of operation of the BG Putty since its prior clearance (K170306).

11.2.1 Device Composition

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000049

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(b)(4)

11.2.2 Chemical Composition

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000050

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(b)(4)

(b)(4)

11.2.3 Physical Properties

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

11.3.1 EIT Cellular Titanium® Cages

The EIT Cellular Titanium® Cervical and Lumbar Cages are manufactured from Titanium 6-Aluminum 4-Vanadium alloy (Extra Low Interstitial), conforming to ASTM Standard F3001.

11.3.2 FIBERGRAFT® BG Putty Bone

As previously cleared, the primary component of FIBERGRAFT® BG Putty is made from 45S5 bioactive glass (M-45 granules and MS-45 microspheres).

11.4 Manufacturing

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000057

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Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4). Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image002.png@01D8C1F1.D6904D90]<http://secure-web.cisco.com/1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=aVS4ag2WlCnvmLd9enMuIzb3QZYVeEr1qJesctXjmvE%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823713143321%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=xH1%2BEJ3faC%2Bdd0IBok9kmmoFYL7f4WYi1RTagW7gO28%3D&reserved=0>.

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Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. The responses

(b)(4)

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024
UY7v6dINLPrzoRYXVRBtppRIrh7_-
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c/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-
web.cisco.com/1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-
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c/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are

(b)(4)

Thanks,

Justin

[cid:image004.png@01D8D317.727FB430]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116 24

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) for your review. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

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www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image007.png@01D8D317.727FB430]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=7Ye8vBjaYdk5NVTV%2BC517EJqpI94k2n6Evka7R8GhUY%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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3. 510(k) COVER LETTER

July 29, 2022

FDA/CDRH/DCC
JUL 29 2022
RECEIVED

U.S Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Traditional 510(k) Submission – Label Expansion – EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty**
Class II per 21 CFR §888.3080, Intervertebral body fusion device, Product Code: ODP, MAX, MQV

Dear Staff:

In accordance with 21 CFR 807 Subpart E, DePuy Synthes Spine is submitting this Traditional 510(k) to expand the indications for use of the EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty. The EIT Cellular Titanium® Cages have been previously cleared in K201605. The FIBERGRAFT® BG Putty has been previously cleared in K170306.

The 510(k) presents clinical data on Prosidyan's FIBERGRAFT BG Putty used with cervical and lumbar interbody cages. Furthermore, it is important to note that DePuy Synthes Spine has acquired Prosidyan, which now allows all change notices to both devices to be controlled by a single entity.

This premarket notification document has been compiled in alignment with the FDA guidance document *Format for Traditional and Abbreviated 510(k)s,* issued on September 13, 2019.

The following table is supplied as suggested in FDA guidance. Additionally, an Acceptance Checklist is provided in Section 3 which references where each of the required elements of the 510(k) is provided.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Question	YES	NO
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?	X	

In accordance with the Medical Device User Fee and Modernization Act of 2002, payment has been arranged for the appropriate user fee for a 510(k) submission. Please reference User Fee Payment ID Number (b)(4)

The terms "substantially equivalent", "similar" and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

One copy of this premarket notification document is provided in electronic form, and one additional copy of this cover letter is provided in paper form.

It is the position of DePuy Synthes Spine that the contents of this submission constitute confidential commercial information. The descriptions and information contained within this submission have not been disclosed to persons outside the Company excepting only paid consultants and/or paid suppliers. DePuy Synthes Spine hereby requests that the Agency maintain the confidentiality of this submission.

If you have any questions about this notification, please contact:

Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DePuy Synthes SPINE
People inspired
COMPANIES OF Johnson & Johnson

325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

Sincerely,

(b)(6)

Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1WXXRYLmklu2BwoWXjI__90sh7U55nW0sGvUQ6d4i1v9bmkgSux7tT_OXhtm9XrvFXM_LUYOB6p1wcgwBWzY0KAsPhftmWrWXouysKtB98FEohttZTnGgAEFTQTmfKyURMCJCw35K6DYykhHISWt2RlMgl_GSNbHTPmOwi2MNZCFPLqh7u8MqfBMDH2TaNJkLmEXZ4fkLzKiEkrx9QdCLR5vZkuAhjOYtoDHjxZt252A/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1vZRO7mSPzk_mXCIjIU_FQ8JfMakCg_H0j8YYEmgivN0o6byS3k1B8jKOKAFmZs-BaM9dY-UTf26_IQJyrH8Uu5yb_WqsvPhjXP_8DFLOHiiRm5Eces70FOZaZZOHGGVel3cG4jp7tPXytjQCsi-EcrWrhob5TPQA99KbsiN2W3ezpI9aiVE7bWQtTIDgvtdT1WLNDEAGrInAbUO8o4ezFdoII5y1qwVm4OUSBVpRNXU/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

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CONDUIT™ ALIF System

(b)(4)

Surgical Technique

DePuy Synthes

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CONDUIT™ Cervical System

(b)(4)

Surgical Technique

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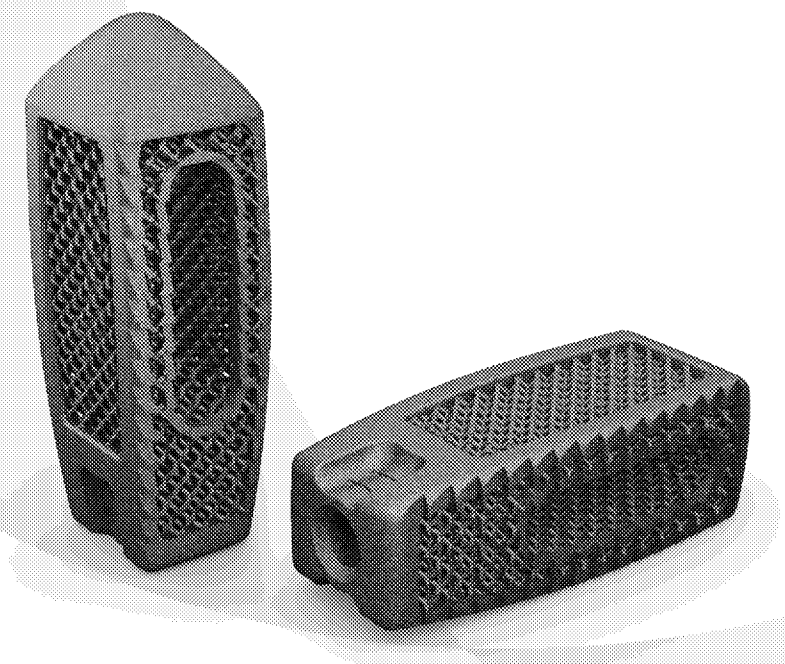
CONDUIT™ Straight TLIF / PLIF System

(b)(4)

Surgical Technique



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CONDUIT™ Curved TLIF System

(b)(4)

Surgical Technique

DePuy Synthes

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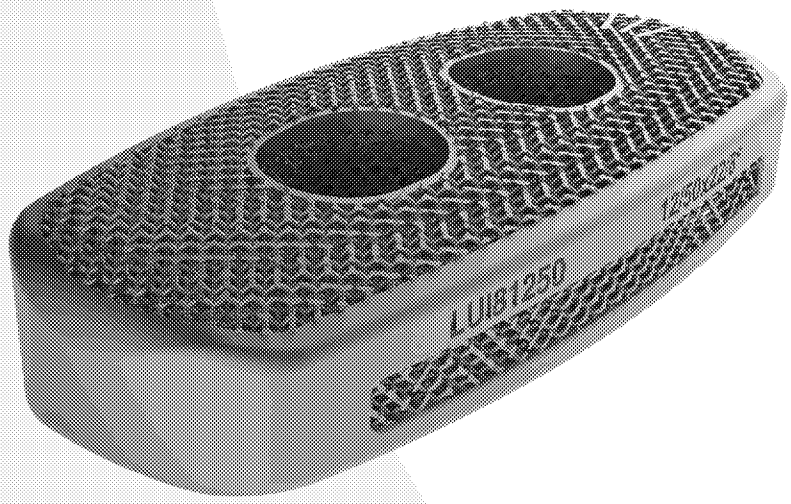
CONDUIT™ Lateral System

(b)(4)

Surgical Technique



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Hi Justin and Philip,

Apologies as I do have one more minor ask. Would it be possible to point me in the direction of your submission that contains information on the (b)(4) (b)(4) you please provide that information?

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

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Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8D9A0.13200550]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<http://secure-web.cisco.com/1NCywdwec0hmbg4QfZv592mOqJ850t6OGY4a9bhC4WnQ625tnb1NRDj8azRDIJHYDOW84DqGyNSqUC7UI2mczjo4vTpasiELr9are18909HRZ62b2XkkVQf7hLPljPHFIQwGdGZLqW7fj7hAvoDxjMxC-eQHF44_DeIedStzndZ6inA7StnsVApslm2AsXKZfmMFKgaqggexRzjmIr7UpWA/http%3A%2F%2Fwww.eventleaf.com%2Fe%2FNASSnetworking>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. **(b)(4)** are attached to this email for your review.

Thanks,

Justin

[cid:image007.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981164112%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gN18pG0poyqW0njZ%2FqqKqsink8WnEwGWEw94pkMohBg%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dMtpztD4aXZhAUtxppCDzG94ER1vwlRI1kw2hLVWsAY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. The responses

(b)(4)

Thanks,

Justin

[cid:image009.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty -

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

[cid:image010.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5h%2BogPYsUJaOfCE%2BtSo9cxzBVJZwJVIuR6ksX5Qq4Ls%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5h%2BogPYsUJaOfCE%2BtSo9cxzBVJZwJVIuR6ksX5Qq4Ls%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image011.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=4wZ1DFFPDhBIeN9ESwuTQvmTeVwbH%2B4SmBY527FrsEI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=4wZ1DFFPDhBIeN9ESwuTQvmTeVwbH%2B4SmBY527FrsEI%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981945248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gTqsRChaTBCXGYdD3jGbPYS1hmU1fLGFTMOcmxQS81s%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

CONDUIT™ Cervical Cage

Indications for Use *(Describe)*

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - Tl. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ ALIF Cage

Indications for Use *(Describe)*
The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ TLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ LLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
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Device Name
CONDUIT™ T/PLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

FIBERGRAFT™ BG Putty

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS

Indications for Use *(Describe)*
FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS Cannula

Indications for Use *(Describe)*
The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Records processed under FOIA Request 2025-4391, Released by CDRH on 10-15-2024

Prosidyan®	Type: Technical Report
	Title: **FIBERGRAFT® BG Putty, BG Putty GPS, and GPS Cannula Real Time Aging (b)(4) - Package Testing & Label Integrity**
	Document No: (b)(4) / Revision No: (b)(4)

Approvals	Date
(b)(4)	

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

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Records processed under FOIA Request 2023-4334 Released by CDRH on 10-15-2024

(b)(4)

Month Real Time Aging Shelf Life Evaluation

for the

Prosidyan, Inc.

FIBERGRAFT® BG Putty GPS

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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FIBERGRAFT™ BG Putty
BONE GRAFT SUBSTITUTE
INSTRUCTIONS FOR USE

DESCRIPTION

FIBERGRAFT™ BG Putty is a synthetic bone graft substitute made from 45S5 bioactive glass. The implantable material is provided as a premixed putty of bioactive granules in a polymer bioactive OSSIGLIDE™ carrier.

Each granule in FIBERGRAFT™ BG Putty is created from a matrix of bioactive glass fibers that are processed to create an ultra-porous granular structure, which is designed to have an adequate structural integrity for its application as a bone graft substitute material, while optimizing radiopacity and resorption.

FIBERGRAFT™ BG Putty is to be used as supplied without the addition of fluids. For use in posterolateral spine fusion application, FIBERGRAFT™ BG Putty must be mixed with autograft.

INTENDED USE AND INDICATIONS

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

CONTRAINDICATIONS

FIBERGRAFT™ BG Putty is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- Growth plate fractures
- Segmental defects
- Load-bearing defects where rigid stabilization is not possible
- Significant vascular impairment proximal to the bony void or gap
- Metabolic or systemic bone disorders that affect bone or wound healing
- Osteomyelitis at the graft site
- Intraoperative soft tissue coverage is not planned or possible
- FIBERGRAFT™ BG Putty would come in direct contact with the articular space
- Conditions in which general bone grafting is not advisable
- Sensitivity to any component of FIBERGRAFT™ BG Putty

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WARNINGS

- Do not use FIBERGRAFT™ BG Putty to support reduction of a defect site. Use rigid fixation techniques as needed to achieve defect stabilization in all planes.
- Do not attempt to gain screw purchase into FIBERGRAFT™ BG Putty. Screws must gain purchase in the host bone. FIBERGRAFT™ BG Putty does not have sufficient mechanical strength to support screw purchase.
- Do not use FIBERGRAFT™ BG Putty to repair bone defects where soft tissue coverage cannot be achieved. Complete postoperative wound closure is imperative.
- FIBERGRAFT™ BG Putty is intended for single use only. Discard unused material; do not re-use or re-sterilize.
- Do not add or mix with liquids; mixing with liquids may affect the handling properties of FIBERGRAFT™ BG Putty.
- Do not use in infected sites.

PRECAUTIONS

- Evaluate the risk/benefit ratio of implanting FIBERGRAFT™ BG Putty in a patient with a pre-existing calcium metabolism disorder (e.g., hypercalcemia).
- Fully fill the defect site to obtain maximum contact between FIBERGRAFT™ BG Putty and host bone; however, do not over-fill the implant site. Doing so may lead to bone formation in unintended areas.
- The radiopacity of FIBERGRAFT™ BG Putty is comparable to that of bone and diminishes as the product is resorbed and replaced by bone. During roentgenographic evaluations, be aware that FIBERGRAFT™ BG Putty may mask underlying pathologic conditions.
- Do not use after the printed expiration date on the label.
- For interbody procedures, FIBERGRAFT™ BG Putty should only be used by physicians who are experienced with intervertebral body fusion procedure. Insufficient experience and/or training may lead to a higher incidence of adverse events.

ADVERSE EVENTS

The following adverse events have been reported to result from bone grafting procedures and; therefore, may be potential complications for FIBERGRAFT™ BG Putty. These potential complications are superficial wound infection, deep wound infection, osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst formation, hematoma, and cellulitis. Any of these conditions may require an additional surgical procedure and may also require removal of FIBERGRAFT™ BG Putty.

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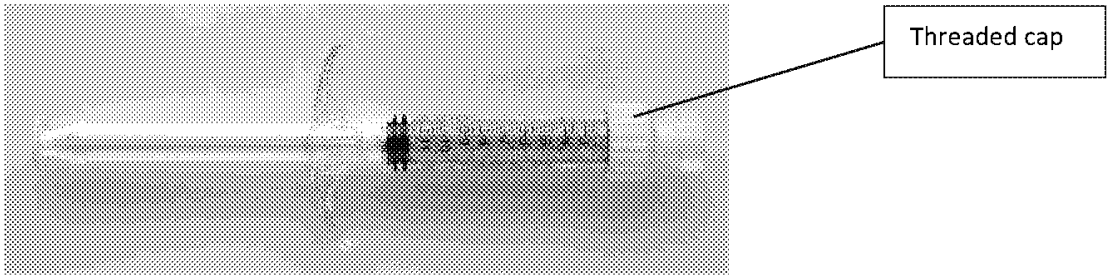
DIRECTIONS FOR USE

- Inspect the package for structural integrity prior to use. If the package, tamper evident seal or the seal of any container is damaged, consider the device to be non-sterile and do not use the device.
- Perform a radiographic review and assess the extent of the defect site.
- Determine the required amount of FIBERGRAFT™ BG Putty. The bone graft substitute comes packaged in a syringe with a removable threaded cap. Unscrew the threaded cap to dispense the product.



- **For pelvis and extremities applications**, use the FIBERGRAFT™ BG Putty as provided.
- **For posterolateral spine applications**, place the following in a tray and mix: 1 parts FIBERGRAFT™ BG Putty with 1 parts autograft by volume.
- Gently pack the FIBERGRAFT™ BG Putty into the site, molding to the desired contours.
- Remove any excess material and close as per standard practice.
- FIBERGRAFT™ BG Putty should fill the defect and contact viable bone as much as possible, but do not overfill. Some bleeding should be observed originating from the host bone to indicate viability.
- Regeneration is expected when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not over compress into the site such that it may be forced into unintended areas.
- Close the surgical site.

For use in the intervertebral disc space:

For interbody fusion, the bone graft is gently packed inside the cavity of the intervertebral body fusion device(s). Aside from the bone graft application, standard instrumentation and surgical technique for the cervical interbody fusion procedure should be followed.

- Determine the required amount of FIBERGRAFT™ BG Putty based on the intervertebral body fusion device cavity size and the height.
- To dispense the product, unscrew the threaded cap.
- Once dispensed, the product can be gently placed into the intervertebral body fusion device(s) using a sterile-gloved hand or with sterile instrumentation as desired by the surgeon.
- Pack the FIBERGRAFT™ BG Putty into the intervertebral body fusion device(s) and attach the intervertebral body fusion device(s) to the inserter per the intervertebral body fusion device manufacturer's instructions for use.
- The intervertebral disc and vertebral endplates are prepared by the surgeon per the standard surgical technique. Some bleeding should be observed originating from the vertebral end plates to indicate viability. Regeneration will occur best when blood and blood vessels can infiltrate the graft material.
- Insert the FIBERGRAFT™ BG Putty filled intervertebral body fusion device(s) into the prepared disc space.
- Note: for non-cervical levels, also fill the remaining intervertebral disc space with additional FIBERGRAFT™ BG Putty as appropriate using sterile instrumentation.

These instructions are intended as guidelines for the use of FIBERGRAFT™ BG Putty as a part of established techniques. They are not intended to replace or change standard grafting techniques associated with instrumented stabilization

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STERILIZATION

- FIBERGRAFT™ BG Putty is provided sterile by exposure to gamma radiation.
- Inspect the package for structural integrity prior to use. If the package, tamper evident seal or the seal of any container is damaged, consider the device to be non-sterile and do not use the device.
- Do not re-sterilize FIBERGRAFT™ BG Putty by any method.

STORAGE

Store at ambient temperature and humidity.

CAUTION

- Rx ONLY.
- Do not use if product box is open.
- Practice proper sterile maintenance procedures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SYMBOLS GLOSSARY

REF	Catalog number
LOT	Batch code
	Use by YYYY-MM-DD
	Manufacturer
Rx ONLY	Prescription use only
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Consult instructions for use
	Read enclosed instructions for use
	Do not reuse
	Do not resterilize

HOW SUPPLIED

FIBERGRAFT™ BG Putty is available sterile for single use in volumes ranging in size from 1cc to 11cc.

US PATENTS PENDING

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Prosidyan, Inc.
41 Spring Street, New Providence, NJ 07974
Tel. 908-517-3666, Fax 908-396-1151

Prosidyan®

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Prosidyan®

FIBERGRAFT™ BG Putty GPS
INSTRUCTIONS FOR USE

DESCRIPTION

FIBERGRAFT™ BG Putty GPS is a purely synthetic bone graft substitute made from 45S5 bioactive glass. The implantable material is provided as a premixed putty of bioactive granules in a polymer bioactive OSSIGLIDE™ carrier.

Each granule in FIBERGRAFT™ BG Putty GPS is created from a matrix of bioactive glass fibers and that are processed to create an ultra-porous granular structure, which is designed to have an adequate structural integrity for its application as a bone graft substitute material, while optimizing radiopacity and resorption.

FIBERGRAFT™ BG Putty GPS is to be used as supplied without the addition of fluids. FIBERGRAFT™ BG Putty GPS is to be provided in a spindle drive syringe and is compatible with the GPS Cannula product.

INTENDED USE AND INDICATIONS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

CONTRAINDICATIONS

FIBERGRAFT™ BG Putty GPS is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- Growth plate fractures
- Segmental defects
- Load-bearing defects where rigid stabilization is not possible
- Significant vascular impairment proximal to the bony void or gap
- Metabolic or systemic bone disorders that affect bone or wound healing
- Osteomyelitis at the graft site
- Intraoperative soft tissue coverage is not planned or possible
- FIBERGRAFT™ BG Putty GPS would come in direct contact with the articular space
- Conditions in which general bone grafting is not advisable
- Sensitivity to any component of FIBERGRAFT™ BG Putty GPS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WARNINGS

- Do not use FIBERGRAFT™ BG Putty GPS to support reduction of a defect site. Use rigid fixation techniques as needed to achieve defect stabilization in all planes.
- Do not attempt to gain screw purchase into FIBERGRAFT™ BG Putty GPS. Screws must gain purchase in the host bone. FIBERGRAFT™ BG Putty GPS does not have sufficient mechanical strength to support screw purchase.
- Do not use FIBERGRAFT™ BG Putty GPS to repair bone defects where soft tissue coverage cannot be achieved. Complete postoperative wound closure is imperative.
- FIBERGRAFT™ BG Putty GPS is intended for single use only. Discard unused material; do not re-use or re-sterilize.
- Do not add or mix with liquids; mixing with liquids may affect the handling properties of FIBERGRAFT™ BG Putty GPS.
- Do not use in infected sites.

PRECAUTIONS

- Evaluate the risk/benefit ratio of implanting FIBERGRAFT™ BG Putty GPS in a patient with a pre-existing calcium metabolism disorder (e.g., hypercalcemia).
- Fully fill the defect site to obtain maximum contact between FIBERGRAFT™ BG Putty GPS and host bone; however, do not over-fill the implant site. Doing so may lead to bone formation in unintended areas.
- The radiopacity of FIBERGRAFT™ BG Putty GPS is comparable to that of bone and diminishes as the product is resorbed and replaced by bone. During roentgenographic evaluations, be aware that FIBERGRAFT™ BG Putty GPS may mask underlying pathologic conditions.
- Do not use after the printed expiration date on the label.
- For interbody procedures, FIBERGRAFT™ BG Putty GPS should only be used by physicians who are experienced with intervertebral body fusion procedure. Insufficient experience and/or training may lead to a higher incidence of adverse events.

ADVERSE EVENTS

The following adverse events have been reported to result from bone grafting procedures and; therefore, may be potential complications for FIBERGRAFT™ BG Putty GPS. These potential complications are superficial wound infection, deep wound infection, osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst formation, hematoma, and cellulitis. Any of these conditions may require an additional surgical procedure and may also require removal of FIBERGRAFT™ BG Putty GPS.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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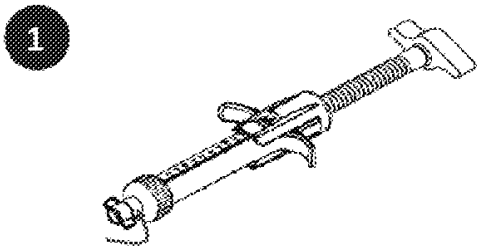
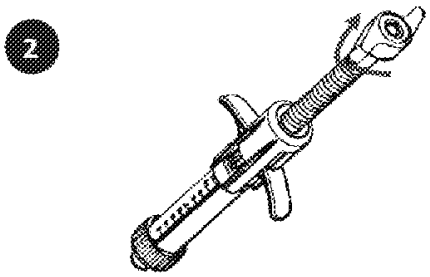
DIRECTIONS FOR USE

- Perform a radiographic review and assess the extent of the defect site.
- Determine the required amount of FIBERGRAFT™ BG Putty GPS. The bone graft substitute comes packaged in a spindle drive syringe with a removable threaded cap. Unscrew the threaded cap to dispense the product.
- FIBERGRAFT™ BG Putty GPS is dispensed by rotating the threaded plunger attached to the syringe.





- **For pelvis and extremities applications**, use the FIBERGRAFT™ BG Putty GPS as provided.
- **For posterolateral spine applications**, place the following in a tray and mix: 1 part FIBERGRAFT™ BG Putty GPS with 1 part autograft by volume.
- Gently pack the FIBERGRAFT™ BG Putty GPS into the site, molding to the desired contours. Remove any excess material and close as per standard practice.
- FIBERGRAFT™ BG Putty GPS should fill the defect and contact viable bone as much as possible, but do not overfill. Some bleeding should be observed originating from the host bone to indicate viability.
- Regeneration is expected when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not over compress into the site such that it may be forced into unintended areas.
- Close the surgical site.

For use in the intervertebral disc space:

For interbody fusion, the bone graft is gently packed inside the cavity of the intervertebral body fusion device(s). Aside from the bone graft application, standard instrumentation and surgical technique for the cervical interbody fusion procedure should be followed.

Determine the required amount of FIBERGRAFT™ BG Putty GPS based on the intervertebral body fusion device cavity size and the height.

- To dispense the product, unscrew the threaded cap.
- Once dispensed, the product can be gently placed into the intervertebral body fusion device(s) using a sterile-gloved hand or with sterile instrumentation as desired by the surgeon.
- Pack the FIBERGRAFT™ BG Putty GPS into the intervertebral body fusion device(s) and attach the intervertebral body fusion device(s) to the inserter per the intervertebral body fusion device manufacturer's instructions for use.
- The intervertebral disc and vertebral endplates are prepared by the surgeon per the standard surgical technique. Some bleeding should be observed originating from the vertebral end plates to indicate viability. Regeneration will occur best when blood and blood vessels can infiltrate the graft material.
- Insert the FIBERGRAFT™ BG Putty GPS filled intervertebral body fusion device(s) into the prepared disc space.
- Note: for non-cervical levels, also fill the remaining intervertebral disc space with additional FIBERGRAFT™ BG Putty GPS as appropriate using sterile instrumentation.

These instructions are intended as guidelines for the use of FIBERGRAFT™ BG Putty GPS as a part of

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established techniques. They are not intended to replace or change standard grafting techniques associated with instrumented stabilization

STERILIZATION

- FIBERGRAFT™ BG Putty GPS is provided sterile by exposure to gamma radiation.
- Inspect the package for structural integrity prior to use. If the package, tamper evident seal or the seal of any container is damaged, consider the device to be non-sterile and do not use the device.
- Do not re-sterilize FIBERGRAFT™ BG Putty GPS by any method.

STORAGE

Store at ambient temperature and humidity.

CAUTION

- Rx ONLY.
- Do not use if product box is open.
- Practice proper sterile maintenance procedures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

SYMBOLS GLOSSARY

REF	Catalog number
LOT	Batch code
	Use by YYYY-MM-DD
	Manufacturer
Rx ONLY	Prescription use only
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Consult instructions for use
	Read enclosed instructions for use
	Do not reuse
	Do not resterilize

HOW SUPPLIED

FIBERGRAFT™ BG Putty GPS is available sterile for single use in volumes ranging in size from 4cc to 11cc.

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Prosidyan, Inc.
41 Spring Street, New Providence, NJ 07974
Tel. 908-517-3666, Fax 908-396-1151

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Prosidyan®

FIBERGRAFT™ BG Putty GPS
INSTRUCTIONS FOR USE

DESCRIPTION

The GPS Cannula is an attachment for use with FIBERGRAFT™ BG Putty GPS. The included accessories are a cannula with a syringe connector and a pusher for the cannula. These accessories aid the delivery of FIBERGRAFT™ BG Putty GPS to bone voids.

INTENDED USE AND INDICATIONS

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

DIRECTIONS FOR USE

- Perform a radiographic review and assess the extent of the target site.
- Determine the required amount of FIBERGRAFT™ BG Putty GPS.
- Remove endcap from the FIBERGRAFT™ BG Putty GPS syringe.
- 100 mm cannula
  1. Attach the 100 mm GPS Cannula to the FIBERGRAFT™ BG Putty GPS syringe tightly as shown in reference images on page 2.
  2. Place the cannula at the target site.
  3. Dispense required quantity of the putty by gently rotating the threaded plunger and observing the graduations on the syringe. Ensure that the putty does not backup in the cannula.
  4. If the cannula and end cap appears loose then tighten the end cap.
  5. Disconnect the cannula from the syringe.
  6. Dispense putty remaining in the cannula with the use of the provided pusher.
  7. Proceed to the overall section on page 2.
- 200mm cannula
  1. Use new cannula for every 4cc of product.
  2. Place the putty at the defect site in 4cc increments.
  3. Remove endcap from the FIBERGRAFT™ BG Putty GPS syringe.
  4. Attach the 200 mm GPS Cannula to the FIBERGRAFT™ BG Putty GPS syringe tightly as shown in reference images on page 2.
  5. Fill the cannula with 4 cc putty by gently rotating the threaded plunger and observing the graduations on the syringe. Ensure that the putty does not backup in the cannula.
  6. If the cannula end cap appears loose then tighten the end cap.
  7. Once required amount of putty is dispensed, disconnect syringe.
  8. Dispense putty remaining in the cannula with the use of the provided pusher to place the putty into the target site.

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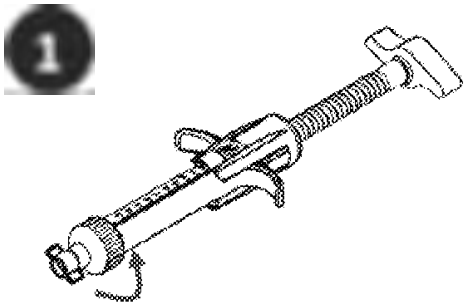
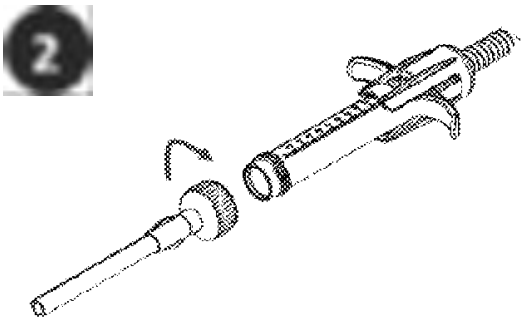
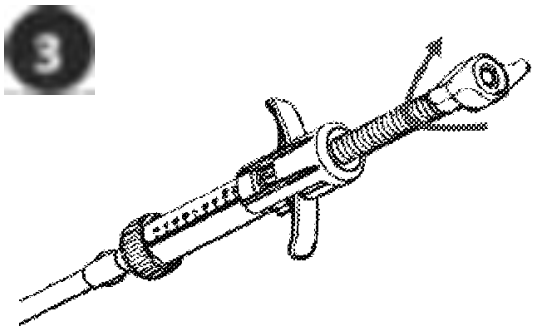
- OVERALL
  1. Gently pack the putty into the target site, molding to the desired contours. Remove any excess material.
  2. FIBERGRAFT™ BG Putty GPS should fill the defect and contact viable bone as much as possible, but do not overfill. Some bleeding should be observed originating from the host bone to indicate viability.
  3. Regeneration is expected when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not over compress into the site such that it may be forced into unintended areas.
  4. Close the surgical site as per standard practice.
  5. These instructions are intended as guidelines for the use of the GPS Cannula with FIBERGRAFT™ BG Putty GPS as a part of established techniques. They are not intended to replace or change standard grafting techniques associated with instrumented



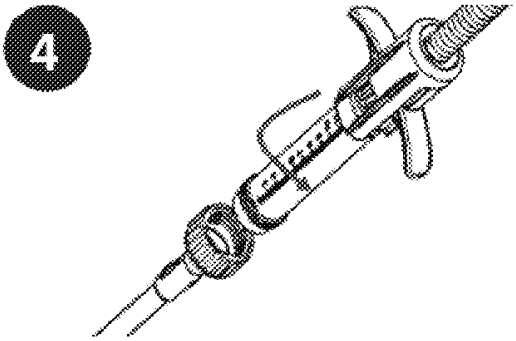
Remove end cap, rotating counterclockwise



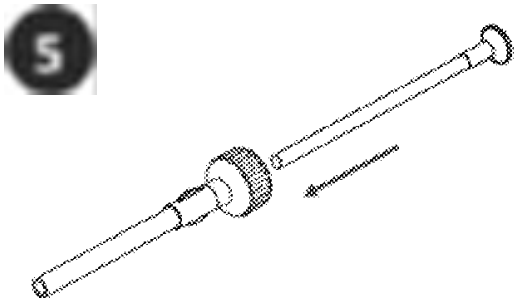
Attach cannula, rotating the end cap clockwise



Dispense Putty by rotating plunger clockwise



Disconnect syringe by holding end cap in place and rotating the syringe barrel counterclockwise



Use plastic pusher to dispense remaining Putty from cannula

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

There are no specific warnings, precautions, or adverse effects associated with the use of the GPS Cannula. The contraindications, warnings, precautions for FIBERGRAFT™ BG Putty GPS are provided.

CONTRAINDICATIONS

FIBERGRAFT™ BG Putty GPS is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- Growth plate fractures
- Segmental defects
- Load-bearing defects where rigid stabilization is not possible
- Significant vascular impairment proximal to the bony void or gap
- Metabolic or systemic bone disorders that affect bone or wound healing
- Osteomyelitis at the graft site
- Intraoperative soft tissue coverage is not planned or possible
- FIBERGRAFT™ BG Putty GPS would come in direct contact with the articular space
- Conditions in which general bone grafting is not advisable
- Sensitivity to any component of FIBERGRAFT™ BG Putty GPS

WARNINGS

- Do not use FIBERGRAFT™ BG Putty GPS to support reduction of a defect site. Use rigid fixation techniques as needed to achieve defect stabilization in all planes.
- Do not attempt to gain screw purchase into FIBERGRAFT™ BG Putty GPS. Screws must gain purchase in the host bone. FIBERGRAFT™ BG Putty GPS does not have sufficient mechanical strength to support screw purchase.
- Do not use FIBERGRAFT™ BG Putty GPS to repair bone defects where soft tissue coverage cannot be achieved. Complete postoperative wound closure is imperative.
- FIBERGRAFT™ BG Putty GPS is intended for single use only. Discard unused material; do not re-use or re-sterilize.
- Do not add or mix with liquids; mixing with liquids may affect the handling properties of FIBERGRAFT™ BG Putty GPS.
- Do not use in infected sites.

PRECAUTIONS

- Evaluate the risk/benefit ratio of implanting FIBERGRAFT™ BG Putty GPS in a patient with a pre-existing calcium metabolism disorder (e.g., hypercalcemia).
- Fully fill the defect site to obtain maximum contact between FIBERGRAFT™ BG Putty GPS and host bone; however, do not over-fill the implant site. Doing so may lead to bone formation in unintended areas.
- The radiopacity of FIBERGRAFT™ BG Putty GPS is comparable to that of bone and diminishes as the product is resorbed and replaced by bone. During roentgenographic evaluations, be aware that FIBERGRAFT™ BG Putty GPS may mask underlying pathologic conditions.

ADVERSE EVENTS

The following adverse events have been reported to result from bone grafting procedures and; therefore, may be potential complications for FIBERGRAFT™ BG Putty GPS. These potential complications are superficial wound infection, deep wound infection, osteomyelitis, nonunion,

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wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst formation, hematoma, and cellulitis. Any of these conditions may require an additional surgical procedure and may also require removal of FIBERGRAFT™ BG Putty GPS.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STERILIZATION

- GPS Cannula is provided sterile by exposure to gamma radiation.
- Inspect the package for structural integrity prior to use. If the package, tamper evident seal or the seal of any container is damaged, consider the device to be non-sterile and do not use the device.
- Do not re-sterilize GPS Cannula or its components by any method.

CAUTION

- Rx ONLY.
- Do not use if product box is open.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

SYMBOLS GLOSSARY

REF	Catalog number
LOT	Batch code
	Use by YYYY-MM-DD
	Manufacturer
Rx ONLY	Prescription use only
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Consult instructions for use
	Read enclosed instructions for use
	Do not reuse
	Do not resterilize

HOW SUPPLIED

GPS Cannula is available in two sizes, 100 mm and 200 mm.

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41 Spring Street, New Providence, NJ 07974
Tel. 908-517-3666, Fax 908-396-1151

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Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

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(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4). Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4231; Released by CDRH on 10-15-2024

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

I'll review when I'm back home in a few hours.

Thanks!
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
202.552.5804

-------- Original message --------
From: "Houck, Jennifer" <Jennifer.Houck@fda.hhs.gov>
Date: 10/6/22 4:24 PM (GMT-05:00)
To: "Desjardins, Philip [JJCUS]" <pdesjard@ITS.JNJ.com>, Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask (b)(4)
(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience a (b)(4)

(b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for thi (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

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To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
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Jennifer,

The updated documents to alig (b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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803 7th Street NW
Washington, DC 20001
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Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
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Jennifer,

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Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

18. PERFORMANCE TESTING – BENCH

18.1 Performance Testing - EIT Cellular Titanium® Cages

There have been no design changes to the EIT Cellular Titanium® Cages since the prior submission (K201605). Because the subject device is identical to the primary predicate in design, the bench testing from prior submissions is adequate to support the current submission. No additional bench testing has been conducted to support this submission.

It is important to note that clinical data is included in **Section 20** of this submission. The clinical data adequately supports the expanded indications proposed; therefore, no additional bench testing is needed.

18.2 Performance Testing - FIBERGRAFT® BG Putty

There have been no design changes to the FIBERGRAFT® BG Putty since the prior submission (K170306). Because the subject device is identical to the previously cleared predicate in design, the bench testing from prior submissions is adequate to support the current submission.

It is important to note that clinical data is included in **Section 20** of this submission. The clinical data adequately supports the expanded indications proposed; therefore, no additional bench testing is needed to support the indications.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000115

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

CONDUIT™ Cervical Cage

Indications for Use *(Describe)*

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - Tl. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ ALIF Cage

Indications for Use *(Describe)*
The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ TLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ LLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ T/PLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

FIBERGRAFT™ BG Putty

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS

Indications for Use *(Describe)*
FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS Cannula

Indications for Use *(Describe)*
The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4) to this email for your review.

Thanks,

Justin

[cid:image002.png@01D8D331.51B40480]<http://secure-web.cisco.com/17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nIoZSsfdPvpfU8XnL1XIQly7oITZfqCM6tu74xkbQGE%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image006.png@01D8D331.51B40480]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=CzsQkN5H1Li8AnN%2FrU7Q8lxOlYWGyFgJ61Sk5Cddc10%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=CzsQkN5H1Li8AnN%2FrU7Q8lxOlYWGyFgJ61Sk5Cddc10%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image008.png@01D8D331.51B40480]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=pCBd2kRj4i%2BjFCTsO87srnaDCo5A3u2fog5qKt8cAVE%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=pCBd2kRj4i%2BjFCTsO87srnaDCo5A3u2fog5qKt8cAVE%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image008.png@01D8D331.51B40480]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=n4HpwMbMfsIGZg03AYhyxwXIi1hVeooMPi4xeqB93kI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=n4HpwMbMfsIGZg03AYhyxwXIi1hVeooMPi4xeqB93kI%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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A%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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ection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C
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=jy9AcIGgk8ttmxpYMUaGTZ2qBTZDHZxZAr%2B1Fwsma1I%3D&reserved=0>.

Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. (b)(4)

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience a (b)(4)
(b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Jennifer,

Thank you for the update. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1QDZT9tqkaH6vZDxc_t1c_cAhTyiir9Hf0WWdEXgJSkbYJ7zmPwV-77VkZ-q9v7w5ZBfnbvQXXMcrJ9oT4j5PL3MsnP_HC6HWt-YGCXqjVHTEgytr6uNs_MvDtZ_eg6QFt_xdLafIb9oPHm3VjzwbzEgABj03ytLCA_maJS28acYE5LoquHaGCqPS-yRu5bGy/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1bBpyGO8Fbcj-BnWM1i5ueOc8ZxWl4J-OMQRq5TzmNzRFQc_gwvwivePXXQdm7p0EQzbEVhHHEnLUGCCywidsOz4eUfYhXyXW4BYMa5RNfam2RMZcDoeRowGnvH-DceimbJUfTIIyjK6LpagYADKBthibFTo5ITc8UJ2I8p-wikIDe1wlb62d9YOgnQrlBoxE/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image005.png@01D8D31E.8355D670]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830361498%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iW6Mrj7EIc424GFd1P%2B4NXfVN5bDHX2pAyv4cbnvPBI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

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803 7th Street NW

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Web: http://secure-web.cisco.com/1QDZT9tqkaH6vZDxc_t1c_cAhTyiir9Hf0WWdEXgJSkbYJ7zmPwV-77VkZ-q9v7w5ZBfnbvQXXMcrJ9oT4j5PL3MsnP_HC6HWt-YGCXqjVHTEgytr6uNs_MvDtZ_eg6QFt_xdLafIb9oPHm3VjzwbzEgABj03ytLCA_maJS28acYE5LoquHaGCqPS-yRu5bGy/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nIoZSsfdPvpfU8XnL1XIQly7oITZfqCM6tu74xkbQGE%3D&reserved=0>

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Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are

(b)(4)

Thanks,

Justin

[cid:image006.png@01D8D31E.8355D670]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=CzsQkN5H1Li8AnN%2FrU7Q8lxOlYWGyFgJ61Sk5Cddc10%3D&reserved=0
>Justin Eggleton

Vice President, Spine Regulatory Affairs

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>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for (b)(4)

(b)(4)

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(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) are attached for your review. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image008.png@01D8D31E.8355D670]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-

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d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517 71
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>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

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Washington, DC 20001

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image015.png@01D8D31E.8355D670]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C8cf807b6d8c54fce717b08daa1502179%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999662830517716%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=n4HpwMbMfsIGZg03AYhyxwXIi1hVeooMPi4xeqB93kI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Jennifer,

The request has been sent to DePuy and we will respond shortly.

Thanks!

Justin

[cid:image003.png@01D8C1F4.0D98FA60]<http://secure-web.cisco.com/1D_QMllAAqJC7lLB1126bUZVzH2GtxR_LT38h_DHHVgwYdxT8hyEYOaaYZKexpsCdEEC4U44ms_CmQSnXEH2Inn7fjT9OdGD1-kJ1Dhf7qdrXK3a8kX1yDa2hAN5gETX7uof9tuM79ISC9XNnCMIHVZI1KbTj0AdepqaaTIjLGDwUTjfbySiGxrtCr3oNZ4qVjSkxG7d8TdydAGIRD6WEMw/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

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Web: http://secure-web.cisco.com/1fGZF7BAOfDOjcVYxtyf2mJIeenEqBoSKuo0jiffnBOMGi8U0I_WPdv_nWK88k6WjTgAaMOEZ62DF9aXjOjqzeeM267Bqq4dkqv11y2twuYfLiAAthSnUzeldbfJzHBZc2zAzd-7gUkmT100xTd82kBsEiDqv6wtVbSHBBG1SH3vxmybj_I5XuwHlLA_6C_REm7K3PyKwxHOD2xlk9Q9rOg/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1D_QMllAAqJC7lLB1126bUZVzH2GtxR_LT38h_DHHVgwYdxT8hyEYOaaYZKexpsCdEEC4U44ms_CmQSnXEH2Inn7fjT9OdGD1-kJ1Dhf7qdrXK3a8kX1yDa2hAN5gETX7uof9tuM79ISC9XNnCMIHVZI1KbTj0AdepqaaTIjLGDwUTjfbySiGxrtCr3oNZ4qVjSkxG7d8TdydAGIRD6WEMw/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) are attached for your review. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1fGZF7BAOfDOjcVYxtyf2mJIeenEqBoSKuo0jiffnBOMGi8U0I_WPdv_nWK88k6WjTgAaMOEZ62DF9aXjOjqzeeM267Bqq4dkqv11y2twuYfLiAAthSnUzeldbfJzHBZc2zAzd-7gUkmT100xTd82kBsEiDqv6wtVbSHBBG1SH3vxmybj_I5XuwHlLA_6C_REm7K3PyKwxHOD2xlk9Q9rOg/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C646de0e164334b6fa3ed08da902a9383%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637980809805223253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YBk7QkTPBGO2ioFUitPI4EwNfrWAJIeESon8lCkmrfM%3D&reserved=0>

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Hello Justin,

I have one minor question in addition to my recently issued request for information. (b)(4)

(b)(4)

Thank you,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

CONDUIT™ Cervical Cage

Indications for Use *(Describe)*

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - Tl. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ ALIF Cage

Indications for Use *(Describe)*
The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ TLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

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See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ LLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

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See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ T/PLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

FIBERGRAFT™ BG Putty

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS

Indications for Use *(Describe)*
FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS Cannula

Indications for Use *(Describe)*
The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Jennifer,

(b)(4) I'll plan to respond tomorrow.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Thursday, October 06, 2022 4:24 PM
To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)
(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience a (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Since you've provided (b)(4)

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM

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To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again fo (b)(4)

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Thursday, October 6, 2022 7:05 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,

Justin

[cid:image002.png@01D8DA2E.15E54F50]<http://secure-web.cisco.com/1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8DA2E.15BC91A0]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Thursday, October 06, 2022 4:24 PM

To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

[cid:image005.png@01D8DA2E.15E54F50]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735467985%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iBcUzsBmz40pXLYQv%2FhyP2wbmLyrtwdjBg6ktOQDdiQ%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735467985%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iBcUzsBmz40pXLYQv%2FhyP2wbmLyrtwdjBg6ktOQDdiQ%3D&reserved=0>

[cid:image004.jpg@01D8DA2E.15BC91A0]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

here<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1NCywdwec0hmbg4QfZv592mOqJ850t6OGY4a9bhC4WnQ625tnb1NRDj8azRDIJHYDOW84DqGyNSqUC7UI2mczjo4vTpasiELr9are18909HRZ62b2XkkVQf7hLPljPHFIQwGdGZLqW7fj7hAvoDxjMxC-eQHF44_DeIedStzndZ6inA7StnsVApslm2AsXKZfmMFKgaqggexRzjmIr7UpWA%2Fhttp%253A%252F%252Fwww.eventleaf.com%252Fe%252FNASSnetworking&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735467985%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=BLq9YQgiFxUESooN3KUfel%2BVvT%2BZ6cpLVPr9L69cs2U%3D&reserved=0>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

(b)(4)

Thanks,

Justin

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024
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n0%3D%7C3000%7C%7C%7C&sdata=j3aP%2FVmZPle9vXGu3dt%2BHFocTEi3Y4jrAMuL0l33F8E%3D&reserved
=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-
web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image008.png@01D8DA2E.15E54F50]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gy%2FFVgIppuhmbYFMrwrOrWbOgHvwFHtgnaCFAgHX1ZI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

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Washington, DC 20001

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www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gy%2FFVgIppuhmbYFMrwrOrWbOgHvwFHtgnaCFAgHX1ZI%3D&reserved=0
>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image008.png@01D8DA2E.15E54F50]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=XTJh1qCXHo44CWctqxaZC7APfeXsz3atwSfwtzSlhxY%3D&reserved=0>Justin Eggleton

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image012.png@01D8DA2E.15E54F50]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=z5aDxlPQpsSqZ1pvDnTRzULS1GIhlX6ZY47RNKZcMzU%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Washington, DC 20001

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Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=OX4S0dInkfz8MopVMBrvJf6tTb1Y2p3ln3ke2xeSZ2E%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thanks,

Justin

[cid:image008.png@01D8DA2E.15E54F50]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A7UShKuxvZewhRVc6qsSFM%2FjQfNih3p1kag84%2F4VgeM%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A7UShKuxvZewhRVc6qsSFM%2FjQfNih3p1kag84%2F4VgeM%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

K222276 – CONDUIT™ Cages and FIBERGRAFT™

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Good morning Justin,

(b)(4)

I'm requesting the above additional information by COB Wednesday August 10, 2022.

I'm available if there are questions regarding this request.

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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3. 510(k) COVER LETTER

July 29, 2022

U.S Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Traditional 510(k) Submission – Label Expansion – EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty**
Class II per 21 CFR §888.3080, Intervertebral body fusion device, Product Code: ODP, MAX, MQV

Dear Staff:

In accordance with 21 CFR 807 Subpart E, DePuy Synthes Spine is submitting this Traditional 510(k) to expand the indications for use of the EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty. The EIT Cellular Titanium® Cages have been previously cleared in K201605. The FIBERGRAFT® BG Putty has been previously cleared in K170306.

The 510(k) presents clinical data on Prosidyan's FIBERGRAFT BG Putty used with cervical and lumbar interbody cages. Furthermore, it is important to note that DePuy Synthes Spine has acquired Prosidyan, which now allows all change notices to both devices to be controlled by a single entity.

This premarket notification document has been compiled in alignment with the FDA guidance document *Format for Traditional and Abbreviated 510(k)s,* issued on September 13, 2019.

The following table is supplied as suggested in FDA guidance. Additionally, an Acceptance Checklist is provided in Section 3 which references where each of the required elements of the 510(k) is provided.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Question	YES	NO
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?	X	

In accordance with the Medical Device User Fee and Modernization Act of 2002, payment has been arranged for the appropriate user fee for a 510(k) submission. Please reference User Fee Payment ID Number (b)(4)

The terms "substantially equivalent", "similar" and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

One copy of this premarket notification document is provided in electronic form, and one additional copy of this cover letter is provided in paper form.

It is the position of DePuy Synthes Spine that the contents of this submission constitute confidential commercial information. The descriptions and information contained within this submission have not been disclosed to persons outside the Company excepting only paid consultants and/or paid suppliers. DePuy Synthes Spine hereby requests that the Agency maintain the confidentiality of this submission.

If you have any questions about this notification, please contact:

Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DePuy Synthes People inspired
SPINE
COMPANIES OF Johnson & Johnson

325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

Sincerely,

(b)(6)

Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16. SOFTWARE

The subject devices do not contain software. This section is therefore not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Justin,

Thanks for this additional piece of information. We appreciate it.

Have a great rest of your week,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Monday, October 10, 2022 8:47 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Friday, October 07, 2022 9:21 AM
To: Justin Eggleton <jeggleton@mcra.com>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Thursday, October 6, 2022 7:05 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4) I'll plan to respond tomorrow.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Thursday, October 06, 2022 4:24 PM
To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask (b)(4)
(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

I'm all good on my end and don't think I'll have any other requests for you. (b)(4)

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)
(b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798

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Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend! (b)(4)
(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: ***https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E***.

Hi Justin,

Thanks for confirming receipt. I'll look forward to your response.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Thursday, August 4, 2022 12:36 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov

Subject: [EXTERNAL] RE: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty - RTA Checklist Interactive Request - Response due COB August 10, 2022

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Jennifer,

Email received and we'll start working on this right away. I'll let you know if any follow-up questions.

Thanks,

Justin

[cid:image008.png@01D8A800.F2897270]<http://secure-web.cisco.com/1uSBUrajOtmFtxgtbJrX_A6tkOJnV91HFujmVsHyuQsoy7YIkll1kWMkY0K2HOyrLp8bXUCwMTKnHxOz4fccnc74V2O7ve0hhLkg5EDMs1eanwKhsHLwld-VhDo0F66dxrrWqYZCAe5NHkSfxPF6MsS1AeKAp017Gh_DeMrqhk1iwzyGSxKI_Jl7XNL7S-krG/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1uSBUrajOtmFtxgtbJrX_A6tkOJnV91HFujmVsHyuQsoy7YIkll1kWMkY0K2HOyrLp8bXUCwMTKnHxOz4fccnc74V2O7ve0hhLkg5EDMs1eanwKhsHLwld-VhDo0F66dxrrWqYZCAe5NHkSfxPF6MsS1AeKAp017Gh_DeMrqhk1iwzyGSxKI_Jl7XNL7S-krG/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Thursday, August 04, 2022 12:06 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty - RTA Checklist Interactive Request - Response due COB August 10, 2022

Good morning Justin,

(b)(4)

I'm requesting the above additional information by COB Wednesday August 10, 2022.

I'm available if there are questions regarding this request.

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.youtube.com%2Fuser%2FUSFoodandDrugAdmin&data=05%7C01%7Cjeggleton%40mcra.com%7C52c83052b85340dddfb508da7633301c%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637952259468669099%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=6ucOM9UNVjCSccIOsgxh8lijKN8tTJI4ZQFGN4ADjac%3D&reserved=0>
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<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F&data=05%7C01%7Cjeggleton%40mcra.com%7C52c83052b85340dddfb508da7633301c%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637952259468669099%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=J5mUDBo3Yd%2FaNpgpdntL8L3pjBm4X8JqxKVvQHwynWk%3D&reserved=0>
[cid:image009.jpg@01D8A800.F27EC410]
<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFDA%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.com%7C52c83052b85340dddfb508da7633301c%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637952259468669099%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=8g5kxooX%2Bf08VAvcFbLIQoGq9x3bpus4xcYoQInwZ6Q%3D&reserved=0>

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend (b)(4). We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
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Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
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Jennifer,

(b)(4). Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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803 7th Street NW
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIC
WO66 RM4452
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3587

Premarket Notification 510(k) Review

Date: October 13, 2022

Reviewer: Jennifer Houck

510(k)# K222276 Subject: Traditional

Applicant: DePuy Spine	**Device Trade Name:** EIT Cellular Titanium Cages; FIBERGRAFT BG Putty
Contact Name: Justin Eggleton	**Contact Title:** Vice President, Spine Regulatory Affairs
Correspondent Firm: Mcra LLC	**Phone:** (202) 552-5800 **Email:** jeggleton@mcra.com
Received Date: July 29, 2022	**Due Date:** October 27, 2022
Pro Code(s): ODP **Class:** II **Reg #:** 888.3080	**Reg Name:** Intervertebral Body Fusion Device
Pro Code(s): MAX Class: II Reg #: 888.3080	Reg Name: Intervertebral body fusion device
Pro Code(s): MQV Class: II Reg #: 888.3045	Reg Name: Resorbable calcium salt bone void filler device

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K201605	MAX, ODP	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage	EIT Emerging Implant Technologies GmbH
K203714	MAX, PHM, OVD, MQV	NuVasive Thoracolumbar Interbody Systems: NuVasive CoRoent Thoracolumbar System, NuVasive CoRoent XL Interfixated System, Brigade System, Brigade Lateral System, BASE Interfixated Titanium System, Coalesce Thoracolumbar Interbody Fusion System, NuVasive Cohere Thoracolumbar Interbody System, NuVasive Modulus XLIF Interbody System, NuVasive Modulus TLIF Interbody System, NuVasive Modulus ALIF System, NuVasive Attrax Putty	NuVasive, Incorporated
K170306	MQV	FIBERGRAFT BG Putty Bone Graft Substitute	Prosidyan, Inc

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

All good, we're always waiting and willing!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

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(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Kind regards,
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Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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I'm also available for any questions related to this request.

Kind regards,
Jennifer

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

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Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E.

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
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Jennifer,

(b)(4)

Thanks,
Justin

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To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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Washington, DC 20001
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

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Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

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Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
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Hi Justin,

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Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
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To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
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Jennifer,

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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803 7th Street NW
Washington, DC 20001
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Thanks for your patience as (b)(4)

(b)(4)

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Kind regards,
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Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this (b)(4)

(b)(4)

Thanks,
Justin

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Vice President, Spine Regulatory Affairs
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Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Since you've (b)(4)

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

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Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
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Kind regards,
Jennifer

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Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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CLINICAL INVESTIGATION REPORT (CIR)

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FIBERGRAFT BG Putty and FIBERGRAFT BG Putty GPS/GPS Cannula Device Listing

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

October 15, 2022

DePuy Spine
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
803 7th St NW
Washington, District of Columbia 20001

Re: K222276
Trade/Device Name: CONDUIT™ Cages and FIBERGRAFT™ BG Putty
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, MQV
Dated: July 29, 2022
Received: July 29, 2022

Dear Justin Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

CONDUIT™ Cervical Cage

Indications for Use *(Describe)*

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - Tl. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ ALIF Cage

Indications for Use *(Describe)*
The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ TLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ LLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K222276

Device Name
CONDUIT™ T/PLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K222276

Device Name

FIBERGRAFT™ BG Putty

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS

Indications for Use *(Describe)*
FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS Cannula

Indications for Use *(Describe)*
The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

B. Date Prepared

September 28, 2022

C. Device Name - CONDUIT™ Cages

Trade/Proprietary Name: CONDUIT™ Cages

Common/Usual Name: Intervertebral body fusion device

Regulatory Class: Class II per 21 CFR §888.3080

Review Panel: Orthopedic

Product Codes: ODP, MAX

D. Device Name - FIBERGRAFT™ BG Putty

Trade/Proprietary Name: FIBERGRAFT™ BG Putty

Common/Usual Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II per 21 CFR §888.3045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Review Panel: Orthopedic

Product Codes: MQV

E. Predicate Device Names

Primary Predicate: DePuy Synthes Spine, K201605, EIT Cellular Cervical Cage, EIT Cellular ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

Additional Predicate: Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Additional Predicate: Prosidyan Inc., K170306, FIBERGRAFT™ BG Putty Bone Graft Substitute

F. Device Description

The CONDUIT™ Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The CONDUIT™ Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous, or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed CONDUIT™ Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The purpose of this submission is to expand the indications for use of the CONDUIT™ Cages to include its use with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bonegraft.

G. Indications for Use

CONDUIT™ Cervical Cage

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

CONDUIT™ ALIF Cage

The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

CONDUIT™ TLIF Cage

The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and

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radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

CONDUIT™ LLIF Cage

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano- scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONDUIT™ T/PLIF Cage

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

FIBERGRAFT™ BG Putty

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty is not indicated for use in load-bearing applications; therefore, standard

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internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ BG Putty GPS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ GPS Cannula

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The purpose of this Traditional 510(k) is to expand the indications for use of the CONDUIT™ Cages to include its used with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The subject device is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. There are no differences in technological characteristics that will raise new concerns of safety or performance.

I. Materials

The CONDUIT™ Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001. The BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicate. The materials and manufacturing process for the CONDUIT™ subject devices are identical to that of the predicate device. Similarly, the materials and composition of the BG Putty device are identical to that of the predicate device and the manufacturing process remains substantially the same as that of the predicate. It is important to note that the manufacturing location of BG Putty was moved from Steris to Prosidyan (now DePuy Synthes), however the process has not changed.

J. Performance Data

The performance of the CONDUIT™ Cervical and Lumbar Cages and the FIBERGRAFT™ BG Putty have been assessed individually within their respective submissions (K201605, and K170306). Clinical data has been utilized to demonstrate the performance and safety of the expanded indications for use, which includes the use of the CONDUIT™ Cages with FIBERGRAFT™ BG Putty. The clinical data includes radiographic and clinical outcomes from a retrospective study and two investigator-initiated studies. The data provided includes 178 subjects and was collected from multiple sites across the United States (CA, TX, FL) to capture a variety of populations with diverse gender and racial/ethnic backgrounds that is representative of the intended users of the subject devices. The results of the data support the performance of the subject devices in intervertebral body fusion based on fusion and adverse event rates. Additional rationales were provided to justify the expanded indications based upon the clinical data results.

K. Conclusion

Based on the body of data presented throughout the submission, it has been determined that the subject devices are substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, and performance data.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

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Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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9. DECLARATION OF CONFORMITY AND SUMMARY REPORT

The standards applicable to the EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty recognized by the FDA are listed below.

Applicable Standards

Standard	Title	FDA Recognition Number
ASTM F3001	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion	8-439
ASTM F1538	Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation	N/A
ISO 11137-1	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	14-528
ISO 11137-2	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	14-409

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000039

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Traditional 510(k) for EIT with FIBERGRAFT BG Putty

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APPENDIX F - FIBERGRAFT Manufacturing Flow Chart

APPENDIX G - FIBERGRAFT BG Putty Biocompatibility Impact Assessment

APPENDIX H - Certificate of Conformance - Prosidyan

APPENDIX I - PPQ Reports - Prosidyan

APPENDIX J - FIBERGRAFT BG Putty CIR

APPENDIX K - FIBERGRAFT BG Putty Real Time Aging Report

APPENDIX L - Engineering Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

Good morning Justin,

(b)(4)

I'm requesting the above additional information **by COB Wednesday August 10, 2022.**

I'm available if there are questions regarding this request.

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
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CDRH | Food and Drug Administration
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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10. EXECUTIVE SUMMARY

Purpose

In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, EIT Emerging Implant Technologies GmbH has compiled a Traditional 510(k) in order to expand the indications for use of the EIT Cellular Titanium® Cages to include use with FIBERGRAFT® BG Putty based on collection of supporting clinical data. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft.

It is important to note that no design changes to the previously cleared EIT Cellular Titanium® Cages, or the FIBERGRAFT® BG Putty are being proposed.

Device Description – EIT Cellular Titanium® Cages

The EIT Cellular Titanium® Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g., using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The EIT Cellular Titanium® Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion, and two of the systems allow for the cages to be packed with allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft.

The 3D Printed EIT Cellular Titanium® Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Device Description - FIBERGRAFT® BG Putty

The FIBERGRAFT® BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT® BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable carrier to form a cohesive material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000040

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Indications for Use

EIT Cellular Titanium® Cervical Cage

The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

EIT Cellular Titanium® ALIF Cage

The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

EIT Cellular Titanium® TLIF Cage

The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000041

surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

EIT Cellular Titanium® LLIF Cage

The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

EIT Cellular Titanium® T/PLIF Cage

The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

FIBERGRAFT® BG Putty

FIBERGRAFT® BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT® BG Putty must be used with autograft in the posterolateral spine.

When used in intervertebral body fusion procedures, FIBERGRAFT® BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Technology

As established within this submission, the EIT Cellular Titanium® Cages and the FIBERGRAFT® BG Putty are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution within the United States. The subject devices are shown to be substantially equivalent and have the same technological characteristics as their predicate devices including size, materials, design, function, and intended use.

Comparison to Predicate

The purpose of this Traditional 510(k) is to demonstrate that the EIT Cellular Titanium® Cages used with the FIBERGRAFT® BG Putty is substantially equivalent to predicate devices for the purpose of introducing to interstate commerce.

The subject devices are substantially equivalent in device indications, manufacturing process, surgical approach, design and performance to the following predicates:

- *Primary Predicate:* DePuy Synthes Spine, K201605, EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

- *Secondary Predicate:* Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

- *Secondary Predicate:* Prosidyan Inc., K170306, FIBERGRAFT® BG Putty Bone Graft Substitute

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000043

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

5. 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

B. Date Prepared

September 28, 2022

C. Device Name - CONDUIT™ Cages

Trade/Proprietary Name: CONDUIT™ Cages

Common/Usual Name: Intervertebral body fusion device

Regulatory Class: Class II per 21 CFR §888.3080

Review Panel: Orthopedic

Product Codes: ODP, MAX

D. Device Name - FIBERGRAFT™ BG Putty

Trade/Proprietary Name: FIBERGRAFT™ BG Putty

Common/Usual Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II per 21 CFR §888.3045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Review Panel: Orthopedic

Product Codes: MQV

E. Predicate Device Names

Primary Predicate: DePuy Synthes Spine, K201605, EIT Cellular Cervical Cage, EIT Cellular ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

Additional Predicate: Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Additional Predicate: Prosidyan Inc., K170306, FIBERGRAFT™ BG Putty Bone Graft Substitute

F. Device Description

The CONDUIT™ Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The CONDUIT™ Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous, or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed CONDUIT™ Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

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The purpose of this submission is to expand the indications for use of the CONDUIT™ Cages to include its use with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft.

G. Indications for Use

CONDUIT™ Cervical Cage

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

CONDUIT™ ALIF Cage

The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

CONDUIT™ TLIF Cage

The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and

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radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

CONDUIT™ LLIF Cage

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano- scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONDUIT™ T/PLIF Cage

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

FIBERGRAFT™ BG Putty

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty is not indicated for use in load-bearing applications; therefore, standard

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internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ BG Putty GPS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ GPS Cannula

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The purpose of this Traditional 510(k) is to expand the indications for use of the CONDUIT™ Cages to include its used with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The subject device is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. There are no differences in technological characteristics that will raise new concerns of safety or performance.

I. Materials

The CONDUIT™ Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001. The BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicate. The materials and manufacturing process for the CONDUIT™ subject devices are identical to that of the predicate device. Similarly, the materials and composition of the BG Putty device are identical to that of the predicate device and the manufacturing process remains substantially the same as that of the predicate. It is important to note that the manufacturing location of BG Putty was moved from Steris to Prosidyan (now DePuy Synthes), however the process has not changed.

J. Performance Data

The performance of the CONDUIT™ Cervical and Lumbar Cages and the FIBERGRAFT™ BG Putty have been assessed individually within their respective submissions (K201605, and K170306). Clinical data has been utilized to demonstrate the performance and safety of the expanded indications for use, which includes the use of the CONDUIT™ Cages with FIBERGRAFT™ BG Putty. The clinical data includes radiographic and clinical outcomes from a retrospective study and two investigator-initiated studies. The data provided includes 178 subjects and was collected from multiple sites across the United States (CA, TX, FL) to capture a variety of populations with diverse gender and racial/ethnic backgrounds that is representative of the intended users of the subject devices. The results of the data support the performance of the subject devices in intervertebral body fusion based on fusion and adverse event rates. Additional rationales were provided to justify the expanded indications based upon the clinical data results.

K. Conclusion

Based on the body of data presented throughout the submission, it has been determined that the subject devices are substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, and performance data.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
July 29, 2022	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B — APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
DePuy Spine		1526439
Street Address		**City**
325 Paramount Dr.		Raynham
State/Province	**ZIP/Postal Code**	**Country**
MA	02767	USA

Contact Name	Contact Title
Philip Desjardins	VP Global Regulatory Affairs
Division Name *(if applicable)*	**Phone Number *(including area code)***
	(202) 589-1005
Fax Number *(including area code)*	**Contact Email Address**
	pdesjard@its.jnj.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
MCRA LLC		
Street Address		City
803 7th St NW		Washington DC
State/Province	ZIP/Postal Code	Country
DC	20001	USA

Contact 1 Name Justin Eggleton	Contact 1 Title Vice President, Spine Regulatory Affairs
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)* 202-552-5800
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address jeggleton@mcra.com
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☒ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	EIT Cellular Titanium® Cages
2	FIBERGRAFT® BG Putty
3	
4	
5	
	Common/Generic Name *(Include if no Trade Name)*

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 K201605	2 K170306	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

ODP, MAX, MQV

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
21 CFR §888.3045, §888.3080	Orthopedic

Device Class

- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

- ☐ New Device
- ☐ STED
- ☐ Post-approval Study Protocol
- ☐ HDE Request for Annual Distribution Number (ADN)
- ☐ Change in Design, Component, or Specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(Specify below)*
- ☐ Location Change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
- ☐ Process Change:
  - ☐ Manufacturing
  - ☐ Packaging
  - ☐ Sterilization
  - ☐ Vendor/Supplier Change
  - ☐ Other *(Specify below)*
- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ PAS update
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(Specify below)*
- ☐ Amendment:
  - ☐ Withdrawal
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Change of Address
  - ☐ Request for Extension
  - ☐ Response to FDA Correspondence
  - ☐ Other *(Specify below)*

☐ Bundle Submission -- *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

- ☐ Original IDE
- ☐ Supplement:
  - ☐ New Study/New Protocol
  - ☐ Change in Correspondent
  - ☐ Change in Manufacturer
  - ☐ Change in Sponsor
  - ☐ Change in Design
  - ☐ Change in Informed Consent
  - ☐ Change in Manufacturing
  - ☐ Change in Protocol
  - ☐ 5-Day Notice – Device or Manufacturing
  - ☐ 5-Day Notice – Protocol
  - ☐ Compassionate Use Request (under an IDE)
  - ☐ Live Case Request
  - ☐ Request Deviation from Protocol
  - ☐ Expansion of Study (Study/Sites)
  - ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*

- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

- ☐ Report:
  - ☐ Adverse Effect
  - ☐ Final, Study Completed
  - ☐ Annual Progress
  - ☐ Interim Progress
  - ☐ Semiannual Investigator List
  - ☐ Failure to Obtain Informed Consent
  - ☐ Compassionate Use Follow-up
  - ☐ Emergency Use
  - ☐ Live Case Follow-up
  - ☐ Completion of Patient Enrollment
  - ☐ Completion of Patient Follow-up
  - ☐ Other *(Specify below)*

- ☐ Amendment to Original IDE:
  - ☐ Amendment Before Final Decision
  - ☐ Response to Refuse to Accept
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Other *(Specify below)*
- ☐ Amendment to Supplement:
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*
- ☐ Amendment to Report:
  - ☐ Response to Deficiency Letter
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

- ☐ Pre-Submission:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Submission Issue Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Additional Information
- ☐ Change in Legal Entity:
  - ☐ Change in Correspondent
  - ☐ Change in Sponsors
  - ☐ Change in Manufacturer
  - ☐ Other *(Specify below)*
- ☐ Agreement Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Determination Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Informational Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-Con
- ☐ Other *(Specify)*:

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SECTION H4 — REASON FOR SUBMISSION – 510(k)

- [x] Original
- [ ] Withdrawal of Original
- [ ] Amendment Before Final Decision:
  - [ ] Change in Ownership
  - [ ] Change in Correspondent
  - [ ] Withdrawal
- [ ] Amendment After Final Decision
- [ ] Supplement:
  - [ ] Response to Refuse to Accept (RTA)
  - [ ] Response to Additional Information Request
  - [ ] Withdrawal
- [ ] Reprocessed SUD
- [ ] Corrective Action
- [ ] STED
- [ ] Third Party *(Complete Section C)*
- [ ] Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K201605	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titani	DePuy Synthes Spine	ODP, MAX
Predicate or Reference Device (B)	K203714	NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty	Nuvasive Inc	ODP, MAX , MQV
Predicate or Reference Device (B)	K170306	FIBERGRAFT® BG Putty Bone Graft Substitute	Prosidyan Inc	MQV

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 — DE NOVO SUBMISSIONS

- [ ] Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- [ ] Withdrawal

SECTION H6 — REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- [ ] **CLIA Categorization Record (CR):**
  - [ ] CLIA Categorization of marketed device (include marketing submission number)
  - [ ] CLIA Categorization of device exempt from premarket review
  - [ ] Additional information regarding an open CR (include CR number)
- [ ] **CLIA Waiver by Application (CW):**
  - [ ] Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - [ ] Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - [ ] Response to FDA correspondence
  - [ ] Additional information regarding an open CW (include CW number)
- [ ] **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☒ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address

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Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use	*If General Use,* Deviation?	Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity		ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use	*If General Use,* Deviation?	Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X		Declaration of Conformity			

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.) Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.) Add Row/Document

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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October 15, 2022</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Jennifer Houck.

 *** This is a system-generated email notification ***

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Records processed under FOIA Request 2023-4381 Released by CDRH on 10-15-2024

Prosidyan®

Type: Process Control Document

Title:

FIBERGRAFT® BG Putty and BG Putty GPS Manufacturing Process Flow

Document No:	Revision No:	DCO:	Effective Date:
(b)(4)		(b)(4)	02/01/22

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Justin,

Thanks for the modified documents. I'll take a look and follow-up with you if we need anything else.

Thank you again and hope you have a wonderful long weekend,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Jennifer,

(b)(4) for your review. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E.

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 7/29/2022 7:56:08 PM
To: jegglwton@mcra.com
CC: DCCLetters@fda.hhs.gov
Subject: K222276 Acknowledgement Letter
Attachments: K222276-Acknowlegement Letter.pdf

July 29, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

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U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

07/29/2022

Justin Eggleton, Vice President, Spine Regulatory Affairs
MCRA LLC
803 7th St NW
Washington, DC 20001
UNITED STATES

Dear Justin Eggleton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K222276
Received: 07/29/2022
Applicant: DePuy Spine
Device: EIT Cellular Titanium Cages; FIBERGRAFT BG Putty

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Jennifer,

(b)(4)

Thanks,

Justin

[cid:image003.png@01D8DC84.CA95AC30]<http://secure-web.cisco.com/1cTrD6j_bqU-BwUr2H_2AUZxQIfvTlrsX2Wr61SGkmvpJDdVAbOtL6zxMUplxTh4griqIyxobClsQbFRq0tuoJ4dyNKg2w_d33r4c9jxcLZw1ac2wHZ_54akTBdfXtg-RsYGAD-OPL6FrTuexoul7YGfqSng6ZJysQbHb0Xy5f0mMdGWMwxNB0DjcVTql-TJInQ5iuGEFSFhvMVHcupNiKpskAFhEiSycSbDHB8H8ffo/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1HIQeQnML24FwjkR0YWKFT0DQT1U7Ed6tp-UPbx1zwA_UzB0xIwOGzkNdZz8EsmRGhUMWiaM3HhnI-X3VquIYhYE65CbZppoUMIeVG_vQiKPhMUNF_Xbg6Z5qwGG7odmSIhavi8urNfKQezC3XJ1C-ya7gPNdQkngabzj3BwZOsPOwMKW21_1XZIVKrrEg7bh4yT6P36RkUBYbTxBrO6xUd7_OP9QQnjH73n3HqS4ovE/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1cTrD6j_bqU-BwUr2H_2AUZxQIfvTlrsX2Wr61SGkmvpJDdVAbOtL6zxMUplxTh4griqIyxobClsQbFRq0tuoJ4dyNKg2w_d33r4c9jxcLZw1ac2wHZ_54akTBdfXtg-RsYGAD-OPL6FrTuexoul7YGfqSng6ZJysQbHb0Xy5f0mMdGWMwxNB0DjcVTql-TJInQ5iuGEFSFhvMVHcupNiKpskAFhEiSycSbDHB8H8ffo/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8DC84.CA95AC30]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<http://secure-web.cisco.com/19LpIpO3bj27LhMaAtLDxyvIqUhyEuUIQfWNdNWKDlw3oetPwng88Z3fGSxnAyLBfQiHHSEmfYrp7cVb8GOGo8wLlJ2RNC6N9yfKyVk6tHkwyLiUSr0prn5OxmUEw_w0CU-dEAAykhAP4a02NZf3p9BqQOXJZy27fJtxom4NNc_ILogWpJJe6jVOsMxZ47ng7G9PfRulOYcS3y7gcy28ePTl55zV_TBA34uhyun_vGyc/http%3A%2F%2Fwww.eventleaf.com%2Fe%2FNASSnetworking>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Friday, October 07, 2022 9:21 AM

To: Justin Eggleton <jeggleton@mcra.com>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Thursday, October 6, 2022 7:05 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,

Justin

[cid:image007.png@01D8DC84.CA95AC30]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456800863679%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=KaNOHGOLm4cFPCuxG7U8Y%2BRe35pYAFVWJirRZw2ixV4%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1HIQeQnML24FwjkR0YWKFT0DQT1U7Ed6tp-UPbx1zwA_UzB0xIwOGzkNdZz8EsmRGhUMWiaM3HhnI-X3VquIYhYE65CbZppoUMIeVG_vQiKPhMUNF_Xbg6Z5qwGG7odmSIhavi8urNfKQezC3XJ1C-ya7gPNdQkngabzj3BwZOsPOwMKW21_1XZIVKrrEg7bh4yT6P36RkUBYbTxBrO6xUd7_OP9QQnjH73n3HqS4ovE/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4

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%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=%2FSPPcfzCHRF18%2Fn2zvXRAi85%2Fz6vE2C3Jn6%2FJ3sF2ds%3D&reserved=0>

[cid:image004.jpg@01D8DC84.CA95AC30]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Thursday, October 06, 2022 4:24 PM

To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

[cid:image009.png@01D8DC84.CA95AC30]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=VozLhNvyvz0Sehy7epRLZGDuaiFnZ53PTUieOnPOXJU%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: http://secure-web.cisco.com/1HIQeQnML24FwjkR0YWKFT0DQT1U7Ed6tp-UPbx1zwA_UzB0xIwOGzkNdZz8EsmRGhUMWiaM3HhnI-X3VquIYhYE65CbZppoUMIeVG_vQiKPhMUNF_Xbg6Z5qwGG7odmSIhavi8urNfKQezC3XJ1C-ya7gPNdQkngabzj3BwZOsPOwMKW21_1XZIVKrrEg7bh4yT6P36RkUBYbTxBrO6xUd7_OP9QQnjH73n3HqS4ovE/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=VozLhNvyvz0Sehy7epRLZGDuaiFnZ53PTUieOnPOXJU%3D&reserved=0>

[cid:image004.jpg@01D8DC84.CA95AC30]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

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From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4) (b)(4)

Thanks,

Justin

[cid:image010.png@01D8DC84.CA95AC30]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=rSQ7J0D9yiGNdT%2FOSjfyZF%2BINRckne27XVJ8ZSE5wmg%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

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Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image011.png@01D8DC84.CA95AC30]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=vlGSgszliBw8mF%2Bt57WWeZaI%2Fc8rqXgmnPNdDHPbziI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1HIQeQnML24FwjkR0YWKFT0DQT1U7Ed6tp-UPbx1zwA_UzB0xIwOGzkNdZz8EsmRGhUMWiaM3HhnI-X3VquIYhYE65CbZppoUMIeVG_vQiKPhMUNF_Xbg6Z5qwGG7odmSIhavi8urNfKQezC3XJ1C-ya7gPNdQkngabzj3BwZOsPOwMKW21_1XZIVKrrEg7bh4yT6P36RkUBYbTxBrO6xUd7_OP9QQnjH73n3HqS4ovE/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801336708%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Vpd%2F0l75GZzaIsxHdJcNk2itRPerUAsByJmRktaHZsg%3D&reserved=0>

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image014.png@01D8DC84.CA95AC30]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801346643%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=fzHIg%2BsSQgVlL1gVWOYX0lh%2BdMPFdun%2Bknrl5xDCrmk%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image008.png@01D8BC80.26B98D80]<http://secure-web.cisco.com/15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

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Ph: (301) 796-3587

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Hi Justin,

Thank you very much! Your response addresses all our questions. We'll be in touch during our substantive review if we have other information requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Wednesday, August 10, 2022 9:29 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov

Subject: [EXTERNAL] RE: K222276 - Clarifying question

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Jennifer,

Thank you for the opportunity to interact on these questions. The formal response is attached to this email. (b)(4)

(b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1HMaygJFzz9d72Vl_STzImoX4VP_4zsjvZfOUMCmx-JZ4iNu31KQLyiW42ojD_NPYKi99rQwtx9udyJREMBzQ94EfyI1tORPWzg5QkT07W4-E7SXqMQnk0JAKh_CxwRtmDsIpy5lhTAIENPJf8ph6BBBRj60BC_9wvW4je2VJqC8t7SGXuCrgZIxOc7VAhpjlcubU2Z1nmPzus8f3NUaLBqmtyUvtg943XSmT_G_BGZg/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Monday, August 08, 2022 12:23 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - Clarifying question

Hello Justin,

I have one minor question in addition to my recently issued request for information.

(b)(4)

Thank you,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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510 (k) – Submission
K222276 -- CON2217385
Clinical Consultation – M.O.

From: Bart Sachs, M.D., MBA; Medical Officer
CDRH / OHT6B / DHT6B1 / Intracolumnar

To: Jennifer Houck; Lead Reviewer
CDRH OHT6C DHT6C

CC: Laura Rose, Ph.D.; Assistant Director, DHT6C1, OHT6C1
Brent Showalter, Ph.D.; Assistant Director, DHT6B / Intracolumnar
Laurence Coyne, Ph.D.; Director, DHT6C, OHT6C
Ronald Jean, Ph.D.; Director, DHT6B, OHT6B

Subject: **K222276 CON2217385**
FIBERGRAFT BG Putty + EIT Cellular Titanium® Cages
DePuy Synthes Spine

Contact:

Mr. Justin Eggleton
Vice President Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
jeggleton@mcra.com

Philip Desjardins
V.P., Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

Date: 07 August 2022

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(5)

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Digital Signature Concurrence Table	
Reviewer Sign-Off	Barton Sachs -S 2022.08.08 17:15:54 -04'00'
Supervisor Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Jennifer,

Email received. Working with DePuy to provide the answers/updated materials in a timely fashion.

Thanks!

Justin

[cid:image003.png@01D8C861.A5AAD990]<http://secure-web.cisco.com/1zcLqL9vKdVUfBPNAgpkZkgAHycbfAlJ19ydfPrqcV0LMbGliQQbW2eZm6dGeOByovTF0XPtwPlgRTIK4gqWVOn2-RrmN99QDr52-YNyFQtoiBK-m4mhrbdiW_LKvgT3LFHQACXsoaKXQ8_9iBwPBdfnavjBsU-hdPRmC0YnRSidFIOFTBmI_usXhwlDOUrPL/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/18iGegDsUOORjfWWl3yyBXo8MMuph7XKuKa1o_rcIcFRlBOIIhQeixB8Tnw_970tJdiM2dRkXxDp1b7lZ1sVohVDHjaiJ49CGNwRKjQPOBdryH59bXRtiUmGuUoYOuoJqraDxFo2swv2jd-Vtpz77Cj58QYK_Hf6E2k0ipKshOlRhVN3EtN53-z0SRluc28vr/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1zcLqL9vKdVUfBPNAgpkZkgAHycbfAlJ19ydfPrqcV0LMbGliQQbW2eZm6dGeOByovTF0XPtwPlgRTIK4gqWVOn2-RrmN99QDr52-YNyFQtoiBK-m4mhrbdiW_LKvgT3LFHQACXsoaKXQ8_9iBwPBdfnavjBsU-hdPRmC0YnRSidFIOFTBmI_usXhwlDOUrPL/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Justin

[cid:image004.png@01D8C861.A5AAD990]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/18iGegDsUOORjfWWl3yyBXo8MMuph7XKuKa1o_rcIcFRlBOIIhQeixB8Tnw_970tJdiM2dRkXxDp1b7lZ1sVohVDHjaiJ49CGNwRKjQPOBdryH59bXRtiUmGuUoYOuoJqraDxFo2swv2jd-Vtpz77Cj58QYK_Hf6E2k0ipKshOlRhVN3EtN53-z0SRluc28vr/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4DqavggjD8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for the (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,

Justin

[cid:image010.png@01D8C861.A5AAD990]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/18iGegDsUOORjfWWl3yyBXo8MMuph7XKuKa1o_rcIcFRlBOIIhQeixB8Tnw_970tJdiM2dRkXxDp1b7lZ1sVohVDHjaiJ49CGNwRKjQPOBdryH59bXRtiUmGuUoYOuoJqraDxFo2swv2jd-Vtpz77Cj58QYK_Hf6E2k0ipKshOlRhVN3EtN53-z0SRluc28vr/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image014.png@01D8C861.A5AAD990]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=7Ye8vBjaYdk5NVTV%2BC517EJqpI94k2n6Evka7R8GhUY%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/18iGegDsUOORjfWWl3yyBXo8MMuph7XKuKa1o_rcIcFRlBOIIhQeixB8Tnw_970tJdiM2dRkXxDp1b7lZ1sVohVDHjaiJ49CGNwRKjQPOBdryH59bXRtiUmGuUoYOuoJqraDxFo2swv2jd-Vtpz77Cj58QYK_Hf6E2k0ipKshOlRhVN3EtN53-z0SRluc28vr/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=7Ye8vBjaYdk5NVTV%2BC517EJqpI94k2n6Evka7R8GhUY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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[cid:image016.jpg@01D8C861.A5AAD990]<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.facebook.com%2FFDA&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=k0Q9HnsF5%2FYP3e4oVnlRwrWYOk%2Bc4w78xuoL24jcgEQ%3D&reserved=0> [cid:image017.jpg@01D8C861.A5AAD990]
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THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution, copying, or other action based on the content of this communication is NOT AUTHORIZED. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://secure-web.cisco.com/1-qqCysLlN2ak0CSot9kLYa1s6VYt7N9eMgaSqBlnuhSSlaokrAN_myLsmpMIt-zNhwwO2fsXipZFFYH9_84PuMttP1qXveiod_3MLZvWDQ9ATYjfejnv-Ckt_lLGBMN9xcSSHy8Ct7DIbcSJtub7Zy_E3ofjmdAmG_dL5S72odVl8tSNCV228Rio9O3YN1PU/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377272468%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=HnMrDxnkTsKHYlmryhjabAs%2B4W2VECo8uV7aajY%2FZaw%3D&reserved=0>.

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Acceptance Checklist for Traditional 510(k)s

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☒		Pg. 1
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒		All
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒		All
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒		Sec. 3
Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☒			All
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☒			Sec. 5
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒			Sec. 5
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☒			Sec. 4
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☒			Sec. 5
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☒			Sec. 6
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*				☒	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*			☒	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*		☒			
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☒			Sec. 8
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*			☒	
		Comments:					
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).*		☒			Sec. 5

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☒			Sec. 5
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*				☒	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments: No device-specific guidance or special controls documents are in effect at this time.					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒			All
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒			Sec. 11
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒			Sec. 11
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☒			Sec. 11
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR**	☒			Att. L

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*				
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☒			Sec. 11
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒			Sec. 11
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☒			Sec. 11
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **<u>AND</u>** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☒			Sec. 11
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de	☒			Sec. 12

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒			Various
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☒			Sec. 8
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the*	☒			Sec. 8

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☒			Sec. 13
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒			Various
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒			Att. C, D
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☒			Att. C, D
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☒			Att. C, D

		Comments:

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*				☒	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*				
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments: No device-specific guidance or special controls documents are in effect at this time.					
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.				☒	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comment: The subject device is not an in vitro diagnostic device.				
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*		☒			Sec. 14
	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☒ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional*					
	if					
	20.	Assessment of the need for cleaning and subsequent disinfection				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		or sterilization information.					
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*	☒			Sec. 14
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☒			Sec. 14
		c.	Identification of device, and/or accessories, and/or components that are reusable.			☒	
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*					
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☒			Sec. 14
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☒			Sec. 14
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			☒	Sec. 14
		d.	Sterility Assurance Level (SAL) stated	☒			Sec. 14
		e.	Submission includes description of packaging	☒			Sec. 14
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus			☒	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*					
		Comments:						
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*					☒	
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*					
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*					
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*					
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."					
			i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*				
		Comments:						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*				☒	
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*				
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments	(b)(5)				
F.	**Shelf-Life**						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	24.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒			Sec. 14
		Comments:				
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☒			Sec. 14
		Comments:				
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒			Sec. 14
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*		☒			Sec. 15
	Submission states that there: (*one of the below must be checked*) ☒ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*					
	Comments:					
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒			Sec. 15
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☒			Sec. 15
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **<u>OR</u>** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☒			Sec. 15
		Comments:				
H.	**Software**				☒	Section 16
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	☒ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*					
	Comments:					
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern			☒	
		Comments:				
	31.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*			☒	
		Comments:				
I.	**Electrical Safety and EMC**					Sec. 17
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☒ Does not require electrical safety evaluation					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*					
	Comments:					
	32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			☒	
		Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☒ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*						
	Comments:						
	33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **<u>OR</u>** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).				☒	
		Comments:					
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*						
	Comments:						
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒			Sec. 18, 20
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Select "N/A" if the submission does not include performance data.				
		Comments:					
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*				☒	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*				
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				☒	
		a.	Legible reprints or a summary of each article.				
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.				
		Comments:					
	37.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120				
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185				
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				
		Comments: This submission does not contain animal study data in support of clearance.					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	☒ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						1
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility			☒	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			☒	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			☒	
		d.	Analytical specificity			☒	
		Comments: The subject device is not an *in vitro* diagnostic device.					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*				☒	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*			☒	
		b.	The submission includes performance data that addresses			☒	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **<u>OR</u>** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments	(b)(5)				

<u>Decision:</u> Accept_____Refuse to Accept____

Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image002.png@01D8CD9B.AEF22780]<http://secure-web.cisco.com/1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

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Washington, DC 20001

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Web: http://secure-web.cisco.com/1DmyY4NdqfCTGorWnoJDD2zSaVsN6Jjp2hYUdEFhE4SAQWoHIRdNls-30t0s8bflSg0LkAHApVyXOjefVk0GFybkNQDOC2XkTgG-hct7QxLAuemGE6KviQtIa_urN4kEiqxkQt5otcFpzh0EItoG463y7h3HJ1jmYmAkpLG14ZvuaIGxoZ7aarCnh6LisQ3JApsBHUpuymOdNZUpfpa7GAS1pwutnNDIfb12fDiGEb1s/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image005.png@01D8CD9B.AEF22780]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

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Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1DmyY4NdqfCTGorWnoJDD2zSaVsN6Jjp2hYUdEFhE4SAQWoHIRdNls-30t0s8bflSg0LkAHApVyXOjefVk0GFybkNQDOC2XkTgG-hct7QxLAuemGE6KviQtIa_urN4kEiqxkQt5otcFpzh0EItoG463y7h3HJ1jmYmAkpLG14ZvuaIGxoZ7aarCnh6LisQ3JApsBHUpuymOdNZUpfpa7GAS1pwutnNDIfb12fDiGEb1s/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for the (b)(4) Although minor, there

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

(b)(4). Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image006.png@01D8CD9B.AEF22780]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1DmyY4NdqfCTGorWnoJDD2zSaVsN6Jjp2hYUdEFhE4SAQWoHIRdNls-30t0s8bflSg0LkAHApVyXOjefVk0GFybkNQDOC2XkTgG-hct7QxLAuemGE6KviQtIa_urN4kEiqxkQt5otcFpzh0EItoG463y7h3HJ1jmYmAkpLG14ZvuaIGxoZ7aarCnh6LisQ3JApsBHUpuymOdNZUpfpa7GAS1pwutnNDIfb12fDiGEb1s/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

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Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

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Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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5. 510(k) SUMMARY

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510(k) SUMMARY

(b)(4)

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Jennifer,

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Thanks!
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Justin Eggleton
Vice President, Spine Regulatory Affairs
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Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for the revised documents a (b)(4)

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
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Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Thanks! Despite my OOO message, still monitoring for FDA emails so let me know if anything else we can do.

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
202.552.5804

-------- Original message --------
From: "Houck, Jennifer" <Jennifer.Houck@fda.hhs.gov>
Date: 10/13/22 8:58 AM (GMT-06:00)
To: Justin Eggleton <jeggleton@mcra.com>, "Desjardins, Philip [JJCUS]" <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thanks for this additional piece of information. We appreciate it.

Have a great rest of your week,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Monday, October 10, 2022 8:47 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Friday, October 07, 2022 9:21 AM
To: Justin Eggleton <jeggleton@mcra.com>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Thursday, October 6, 2022 7:05 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4) I'll plan to respond tomorrow.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Thursday, October 06, 2022 4:24 PM
To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. **(b)(4)**
(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)
(b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

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Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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Jennifer,

Thank you for the opportunity to interact on these questions. (b)(4)

(b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Monday, August 08, 2022 12:23 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - Clarifying question

Hello Justin,

(b)(4)

Thank you,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Hi Justin and Philip,

Apologies as I do have one more minor ask (b)(4)

(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
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Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

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Jennifer,

Thank you for the update. (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

Record processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
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Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

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Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
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Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: ***https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E***.

Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

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Jennifer,

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Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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SPINE Volume 27, Number 16S, pp S26–S31
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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Overview of the Biology of Lumbar Spine Fusion and Principles for Selecting a Bone Graft Substitute

Scott D. Boden, MD

Study Design. Reviews were conducted.

Objectives. To review the biology of spine fusion healing, and to outline several fundamental principles required for the selection of a bone graft substitute.

Summary of Background Data. More than 200,000 spine fusions are performed each year in the United States. The success of this procedure is limited by morbidity from iliac crest bone graft harvest and a nonunion rate that ranges from 10% to 40%. In recent years, there has been an increased understanding of the biology of spine fusion healing. In addition, there has been a focus on finding suitable substitutes for autogenous iliac crest bone graft to promote spine fusion. The selection of a specific bone graft substitute can be a daunting task for the surgeon.

Methods. The available literature was reviewed and combined with the author's personal experience.

Results. A basic understanding of the biology of healing in different types of spine fusions and the differences between different categories of bone graft substitutes can help surgeons organize the graft selection process.

Conclusions. In general, purely osteoconductive substitutes are less effective in adult posterolateral spine fusions, but may be suitable in the anterior spine when it is rigidly immobilized. Osteoinductive substitutes are more likely to be successful as extenders, enhancers, or substitutes for posterolateral spine fusion. [Key words: animal models, biology, bone graft substitutes, bone morphogenetic proteins, gene expression, osteoconduction, osteoinduction, spine fusion] **Spine 2002;27:S26–S31**

It is estimated that more than 200,000 spine fusion procedures are performed each year in the United States. Posterolateral lumbar intertransverse process arthrodesis is the most common procedure performed, yet failure to achieve a solid bony union (nonunion) occurs in 10% to 40% of patients with single-level fusions, and more frequently when multiple levels are attempted.[15,19,25,26,30,61] This high rate of nonunions indicates that the physiologic, biologic, and molecular events crucial to this process are not adequately understood. A nonunion frequently leads to unsatisfactory resolution of clinical symptoms,[17,22,68] and usually results in greater medical costs and morbidity, as well as the need for additional surgeries.

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The most common clinical approach for preventing nonunions has been the use of internal fixation (*e.g.*, hooks or screws with rods or plates). Although the use of internal fixation has decreased the number of nonunions, it has not eliminated the problem. Nonunions still occur in 10% to 15% of patients.[15,46,65,66] Clearly, other factors must be implicated, yet there is a paucity of knowledge regarding the biologic mechanisms involved.[20,43–45] Such knowledge would be helpful in devising strategies for nonunion prevention and allowing appropriate use of different bone graft substitutes for posterolateral spinal fusion.

The healing of a spine fusion is a multifactorial process, which makes it difficult to study in the clinical setting. The lack of reliable noninvasive techniques for assessing the success or failure of an arthrodesis further limits clinical studies.[16] Thus, an animal model is a practical solution for studying individual factors involved in this complex process.[57] Most models used before 1990 had limited utility for biologic studies for one or more of the following reasons: 1) the successful fusion rate was 100%, which is much higher than that seen clinically; 2) the animals were skeletally immature; 3) the arthrodesis performed was interfacet or interlaminar rather than intertransverse; or 4) the model destabilized the spine and resulted in 0% successful fusions without internal fixation.[35,51,54,55,67] The limitations of these earlier models led to the development of an intertransverse process arthrodesis model that was more clinically applicable to the human situation.[10] The major benefit of this type of model is that nonunions spontaneously occur at a rate comparable with that reported in humans.[10,57]

Biology of Spine Fusion

The rabbit lumbar intertransverse process arthrodesis model has been well characterized using autogenous iliac crest as the graft material. Mechanically solid fusions generally occur by the fourth postoperative week with an overall nonunion rate of 30% to 40%. Radiographic analysis has showed progressive remodeling of bone graft material with time, usually by 10 to 12 weeks, but as in humans, radiographs were accurate in assessing success or failure to attain solid fusion only 70% of the time. This model was further validated using control animals with omission of iliac bone graft placement or omission of the decortication step, which resulted in nonunion in all cases. These negative control animals showed that the surgical exposure alone did not automatically result in spinal fusion. This was a limitation of some previous models. Vascular injection studies indi-

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cated that the primary blood supply to the fusion mass originated from the decorticated transverse processes, not the surrounding soft tissues.[63] The failure to achieve spine fusion in the absence of decortication emphasized the importance of extensive decortication of the posterolateral spine elements (lateral facet, pars interarticularis, transverse process) in providing bone marrow, vascularization, and osteoprogenitor cells to the fusion mass.

Histologic analysis of the rabbit transverse process fusion has showed three distinct and reproducible temporal phases of spine fusion healing.[12] Maturation of the spine fusion was most advanced at the ends of the fusion mass near the transverse processes ("outer" zone). A similar histologic progression occurred in the "central" zone, but was delayed in time. This central "lag effect," with a transient cartilaginous area, may explain why many nonunions occur in the central zone of a fusion mass.

A unique temporal and spatial pattern of osteoblast-related gene expression was observed in an RT/PCR analysis of RNA from the different zones of the fusion mass. A lag effect in gene expression that correlated with the previously observed lag effect in the histologic healing sequence was noted in the central zone as compared with the outer zones of the fusion. As with osteocalcin expression, the peak expression of all genes measured was seen in the central zone 1 to 2 weeks later than the peak in the outer zone. This is consistent with the peripheral to central healing pattern observed histologically for fusions using autogenous bone graft.

Expression of the mRNA of several bone morphogenetic proteins (BMPs) also was studied. In the peripheral zones, BMP-2 mRNA expression was increased during weeks 2 through 6, with peak expression in weeks 3 and 4 (40-fold increase). Whereas BMP-6 in the outer zones had a first peak on day 2 (54-fold) and a second peak (100-fold) during week 5, BMP-6 in the central zone showed an initial peak on day 2 (34-fold), but did not demonstrate the later peak. These findings suggest specific time patterns of expression and probably unique roles for each of the various BMPs during spine fusion. It appears that BMP-6 is somewhat unique in that its mRNA levels demonstrated the earliest peak and greatest relative increase of the BMPs studied. The lower level of BMP-6 expression in the central zone of the fusion mass is correlated with the delayed timing and smaller amount of bone formation in the central zone of the fusion. Thus, the predilection for nonunion in the central zone also is apparent at a molecular biologic level.[50]

Models of Spine Nonunion

There are several models that can produce a higher rate of nonunion. Implanting only 50% of the normal volume of autograft lowered the fusion rate from 70% to 33% in the rabbit model.[39] Excessive spine motion (produced by lifting the rabbits out of their cage daily after surgery) decreased the fusion success rate from 58% to 14% ($P = 0.04$).[21] Moderate systemic nicotine exposure (equaling 1 to 2 packs of cigarettes per day) significantly decreased the rate of successful spine fusion from 56% to 0% ($P = 0.02$) in rabbits.[60] These results highlight the importance of recognizing that each healing environment has unique features, and that bone graft substitutes must be tested in the specific healing environments anticipated to predict efficacy. Ketorolac, commonly used as an intravenous analgesic during the postoperative period, facilitated the fourth nonunion model in the current study. Some nonsteroidal antiinflammatory drugs (NSAIDs) have been shown to inhibit fracture repair.[31,56,62,64] The current author determined that a standard dose (4 mg/kg/day) for 7 days caused a decrease in the successful fusion rate from 75% in the control group to 35% ($P < 0.04$) in the rabbits treated with ketorolac.[40]

In summary, the biology of lumbar spine fusion healing in rabbits has been well characterized with autograft, and important mechanical, vascular, cellular, and molecular influences have been identified. Similar detailed understanding is needed for anterior interbody fusion healing, although this location may be less challenging because of increased bony surface area and compression loading. Bone graft quality, quantity, and host bed vascularity (decortication) are critical and must be assessed carefully by the surgeon. The choice of graft substitutes must be individualized on the basis of the aforementioned factors and the presence of potential local or systemic inhibitory factors.

Augmentation of Bone Healing in the Spine

It is estimated that approximately 500,000 bone graft procedures are performed in the United States each year. Of these bone-grafting procedures, the vast majority (≈50%) are spine fusions, followed by general orthopedic procedures and craniomaxillofacial procedures. This potentially represents a $0.4 to $2 billion per year market for the use of bone repair enhancers or bone graft substitutes (DataMonitor, personal communication).

The most common reason for performing a spinal arthrodesis is either instability (excessive motion) of a spine segment or a deformity that is at risk for progression. The vast majority of fusions are performed to treat degenerative disorders, and the most common site is the lumbar spine. Although spinal fusion is commonly attempted, nonunion is reported to occur in 5% to 45% of patients.[42,52,61,66] Although this may be a clinically disturbing statistic, it makes spine fusion an ideal venue for testing bone augmentation devices. It is far easier to show an improvement in the healing of spine fusion than in the healing of fracture repair, in which the normal healing is quite good. Another rationale for testing bone augmentation in spine fusion is the reality that there is frequently an inadequate supply of autogenous bone graft for performing multilevel spinal arthrodesis. In addition, the morbidity of iliac bone graft harvest is reported to be as high as 30%, with the most frequent complications including chronic donor site pain, infection, fracture, hematoma, and increased operative time and costs.[1,5,23,34,58] The current author estimated that the cost of an iliac crest bone graft harvest is approximately $1500 to $2500.

Currently, there are several competitive strategies either to augment healing or to replace autogenous bone

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Table 1. Potential Roles for Bone Graft Materials

Role	Amount of ABG	Graft Volume	Healing Success
Extender	Usual or less	More or same	Same as ABG
Enhancer	Usual or less	More or same	Better than ABG
Substitute	None	Same or more	Same or better than ABG

ABG = autogenous bone graft.

graft in the spine.[9] The most commonly used strategy for healing enhancement is that of rigid internal fixation. The fixation devices range in cost from $3000 to $6000, and are reported to increase the efficacy or the successful fusion rate by approximately 10%. Biophysical stimulation is another strategy that has been pursued in spine fusion for some time, but without good clinical data to support its use. Currently, the costs estimated for electrical stimulation by either direct current or pulsed electromagnetic fields is approximately $4000 to $5000, and although prospective randomized blinded trials have not yet been completed, the maximum benefit in terms of an increased successful fusion rate is estimated to be approximately 10%.[47,48] Low-intensity ultrasound also has been proposed recently for accelerating the healing of long bone fractures, and some experimental evidence in animal models shows that this may also be a viable enhancement strategy for spine fusion.[27,29]

Currently, a variety of potential bone graft extenders is available. Demineralized bone matrix (DBM) in a variety of forms, each with variable degrees of osteoinductivity, is available through numerous sources. In general, the DBM cost for augmenting a one-level spinal fusion may be as high as $1100, and the current data support the use of DBM as a bone graft extender only and not as a bone graft enhancer or substitute.[49] Similarly, various ceramics such as natural coral (calcium carbonate), coralline hydroxyapatite, or composites such as hydroxyapatite-tricalcium phosphate have been used on a limited basis. Although clinical studies are lacking, limited animal data suggest that these ceramics may be viable as bone graft extenders when mixed with autogenous bone graft, but that they are unlikely to serve as stand-alone bone graft substitutes.[11] Thus, the need for improved bone repair and augmentation in the area of spine fusion is evident. The remainder of this article focuses on issues pertaining to the selection of an acceptable bone graft substitute for patients undergoing various types of spine fusion. For the purposes of this discussion, a graft extender is considered to be a material that allows the use of less autogenous bone graft with the same end result, or one that allows a given amount of autogenous bone to be stretched over a greater area with the same success rate (Table 1). A bone graft enhancer is a device that when added to autogenous bone graft, increases the successful healing rate of autogenous bone graft, using either the usual amount of graft or a smaller amount of bone graft. Finally, a bone graft substitute is a material that may be used entirely in place of autogenous bone graft to achieve the same or a better fusion success rate.

Because prospective randomized clinical trials that isolate the efficacy of individual bone graft substitutes in the spine do not exist, it can be challenging to garner information from the published animal and clinical studies. Several overriding principles should be kept in mind. The mechanism and timing of bone healing may vary considerably depending on the region of the spine. The anterior or middle column of the spine is primarily cancellous bone and load bearing, whereas the posterior column of the spine has a greater combination of cortical bone and a submuscular healing environment frequently under tension. Thus, there is considerable variation in the type of healing and speed of healing because of these biologic and biomechanical differences in healing environment. The three primary locations are the anterior interbody, the intertransverse process, and the interlaminar–facet joint region. As a result of these regional differences, the dosage and the ideal delivery vehicle for bone graft substitutes may differ by location. Again, it cannot be overemphasized that the results of healing for bone graft substitutes or augmentation devices in one region of the spine cannot necessarily be extrapolated for other regions.

In addition to the region of the spine as a cause for differences in healing, the specific patient diagnosis may give rise to variation in healing success. One example is lower lumbar spinal fusion for degenerative spondylolisthesis. This may be associated with increased motion at the intervertebral disc space to be fused, which decreases the rate of successful fusion. Alternatively, a patient with degenerative lumbar disc disease and disc collapse may actually have decreased disc motion, which may result in an increased likelihood of obtaining a solid fusion. The risks of neurologic complication, which is the most serious complication resulting from spine surgery, also is dependent on location. Cervical and thoracic spine fusions, particularly in the anterior column, carry some risks of spinal cord injury. In contrast, the structure at risk in the lumbar spine generally is the cauda equina, which is a more tolerant neurologic structure.

Another issue unique to spine fusion is the increased difficulty in the actual assessment of intervention efficacy. It is not always obvious when a solid fusion has been obtained, as opposed to a pseudarthrosis or nonunion. Unfortunately, the vast majority of noninvasive evaluation methods are inaccurate. It is reported that plain radiographs carry an accuracy no greater than 70% for predicting whether a spine fusion is solid.[16,18,28,52] Although the current author believes empirically that CT scanning is a more accurate method, there are no good data available to qualify this increased accuracy in the assessment of spine fusion. Another confounding variable involves the frequent dissociation between measurement of an augmentation device's success (*i.e.*, solid spine fusion) and clinical outcome (*e.g.*, decreased pain or increased function). This dissociation is particularly germane to spine fusion, and is substantiated further by the lack of clinical consensus as to the appropriate indications for spine fusion.[24]

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Selecting a Bone Graft Substitute: The Burden of Proof

The donor site morbidity, limited supply, and imperfect success rate of autogenous bone graft has led to the commercialization of a variety of bone graft substitutes. These graft alternatives have undergone varying degrees of regulatory scrutiny, so their true safety and effectiveness in patients may not be known before their use by orthopedic surgeons. Moreover, given the different categories of bone graft substitutes and the seemingly similar products within each category, product differentiation has become increasingly varied for the practicing spine surgeon. This section is intended to suggest a framework of principles for considering the burden of proof necessary to allow clinicians to make reasonable choices when deciding on osteoinductive bone graft substitutes.

Osteoconductive substitutes may be used as scaffolds to deliver bone growth factors. These materials facilitators for bone formation, but do not contain growth factors that can attract osteoblast precursor cells and initiate osteoblast differentiation. Osteoconductive materials include collagen, ceramics, polymers, and coral, whereas osteoinductive substitutes contain one or more growth factors such as bone morphogenetic proteins (BMPs) capable of independently attracting precursor cells and inducing new bone formation. Whereas numerous growth factors may be involved in new bone formation including platelet derived growth factor (PDGF), transforming growth factor-beta (TGF-β), and vascular endothelial growth factor (VEGF), evidence suggests that only the BMPs are capable of initiating the entire process of new bone formation.[6,7,9,13,36] Lower doses of the BMPs are contained in demineralized bone matrix. They can be found in higher doses as recombinant (genetically engineered) proteins or purified extracts from bone. These materials are being studied in prospective trials and should soon be available for selected uses.

For understanding the burden of proof, the first principle to consider is that different healing environments (*e.g.*, metaphyseal defect, long bone fracture, interbody spine fusion, and posterolateral spine fusion) have increasing levels of difficulty in forming new bone. For example, a metaphyseal defect permits the successful use of many purely osteoconductive materials. In contrast, a posterolateral spine fusion environment generally does not tolerate the use of purely osteoconductive materials as stand-alone substitutes, and only sometimes permits their use as bone graft extenders. Thus, validation of any bone graft substitute in one clinical anatomic site may not be predictive of its performance in another location. Accordingly, surgeons must be very careful in using graft substitutes that have not been tested definitively in the particular healing environment wherein they are about to use it. Most of the osteoconductive substitutes used currently in the spine have been validated only in nonspine locations.

The second principle to consider is the burden of proof required from preclinical studies to justify the use of an osteoinductive graft material or the choice of one brand over another. An osteoinductive material, by definition, must contain one or more growth factors including BMPs that can induce *de novo* ectopic bone formation through differentiation of progenitor cells into osteoblasts. Although not commonly recognized, evidence clearly suggests that it is much harder to make bone in humans than in cell culture or rodent models.[8] It is generally accepted that in lower vertebrates, bone heals more readily than in humans. Some osteoinductive materials (*e.g.*, DBM and rhBMP-2) have been successful in lower vertebrates, but have failed to achieve the same result in primates.[2–4] Findings also have shown the rhesus monkey also to be an acceptable model for human bone remodeling and osteoporosis.[32,33,37,38,53,59]

Only human trials can determine the efficacy of osteoinductive materials in humans. However, a hierarchy of testing credibility exists, ranging from cell culture assays of bone markers and the rat ectopic bone induction assay, as the least predictable tests, to rabbit ulnar defect, rabbit

Table 2. Burden of Proof for Osteoinductive Bone Graft Materials for Spine Fusion

Model	Burden of Proof
Cell culture	Establish that a protein is osteoinductive if bone nodules are the endpoint. If surrogate endpoints are used (alkaline phosphatase or osteocalcin production, these assays are less reliable.
Rat ectopic assay	Establish feasibility of *in vivo* ectopic bone induction. Because rats heal in only 2–3 weeks, issues of premature carrier resorption or compressibility may not be detected in rapidly resorbing carriers. Also, slower resorbing carriers may not form as much bone because the carrier is still occupying much volume in the implant.
Rodent spine fusion	Establish feasibility of successful spine fusion in environment with motion and/or loading. Healing time frame is longer than rat, but still only 4–8 weeks and thus same issues to do with carrier resorption time apply. Useful if detailed biomechanical testing is required.
Large animal model	Establish efficacy in spine fusion model with internal fixation if needed. Internal fixation not practical in most rodent models. Larger animals do not necessarily present a more challenging healing environment and are not more predictive of responses in humans compared with rodents. Useful if detailed biomechanical testing is required.
Nonhuman primates	Nonhuman primates, especially rhesus monkeys, have similar osteoinduction responsiveness, healing time, and carrier resorption behavior to humans. Osteoinductive growth factors require 10–15-fold higher concentrations to achieve comparable results in primates as seen in rodents. Successful doses in rhesus monkeys have translated well into required doses for BMPs in human clinical trials.
Human clinical trials	The ultimate proof lies in a human clinical trial. Doses, carrier requirements, and the need for supplemental internal fixation may vary based on anatomic location in the spine, patient diagnosis, and presence of healing deterrants (smoking, steroids, diabetes, etc).

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spine fusion, and large animal long bone–spine fusion, which have intermediate predictability of efficacy in humans (Table 2). Nonhuman primate long bone, interbody spine, and posterolateral spine fusion models offer the highest challenge and therefore the highest predictability of success in humans.[14,41] It is most important to understand that failure of an osteoinductive material to induce bone in any of these progressively challenging models usually means that it will fail at all higher levels. Unfortunately, successful bone induction at any level does not infer success at the next most stringent level. Only testing at the next level can answer that question. Thus, when differentiating between brands of similar osteoinductive products that have not been validated in human clinical trials, the surgeon should strongly consider choosing the product that satisfied the highest burden of proof in preclinical studies within the aforementioned hierarchy.

The third principle involving the burden of proof specifically pertains to products not currently subject to high levels of regulation such as demineralized bone matrix (DBM) and platelet gels containing "autologous growth factors." Such products are considered to involve minimal manipulation of cells or tissue, and thus are regulated as tissue rather than devices. As a result, no standardized burden of proof level for safety or effectiveness required is before these products are marketed and used in human patients. Although it may be true that such products meet the technical definition of "minimal manipulation," thereby escaping strict regulation, DBM and "autologous growth factor" platelet concentrates are being marketed and used for their biologic (osteoinductive) effects, not as simple tissue transplants or means of augmentation. Consequently, there is a risk that products or certain brands of products may not produce the expected result in humans when there has been little or no animal testing in the relevant and more challenging models. Many investigators in this field believe that minimal standards demonstrating some level of osteoinductivity (bone induction) should be developed for such products. If surgeons do not demand this soon, or if the manufacturers do not institute this in the near future, these products may risk being more highly regulated by the FDA, making them less accessible to surgeons and patients.

■ Key Points

- A basic understanding of the biology of healing in different types of spine fusions and the differences between different categories of bone graft substitutes can help surgeons organize the graft selection process.
- In general, purely osteoconductive substitutes are less effective in adult posterolateral spine fusions, but may be suitable in the anterior spine when it is rigidly immobilized.
- Osteoinductive substitutes are more likely to be successful as extenders, enhancers, or substitutes for posterolateral spine fusion.

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OPERATION FOR POTT'S DISEASE OF THE SPINE

M. McE., aged 51. In August, 1910, a diagnosis, borne out fully by the patient's history, of Pott's disease was made in the case of this patient, and he was admitted into the wards of the Montreal General Hospital. At that time he made the following complaints: (1) he had been suffering from an almost continuous burning pain in his back and under the sternum for twelve months; (2) during this period he had lost about forty pounds in weight.

On admission there was found to be a partial dulness from the 1st to the 4th rib on the right, and from the 1st to the 5th on the left. Over these areas the breath sounds were harsh and of a somewhat bubbling character. The spines of the 1st, 2nd, 3rd, and 4th dorsal vertebræ were prominent and somewhat enlarged. The 10th, 11th, and 12th dorsal spines were also prominent and presented a somewhat similar condition, whereas the 5th, 6th, 7th, and 8th spines were at a much lower level and made a hollow. Over this hollow there was tenderness on pressure. The knee jerks were somewhat increased. The other reflexes and sensations were normal.

The possibilities for the treatment of the tuberculous lesion in the spine of this patient did not seem hopeful. It was useless to attempt fixation by plaster, because of the age and disposition of the patient, and the position of the lesion was not favourable for such form of treatment. Fixation by a brace also was out of the question. Recumbency, with extension and counter extension, was, therefore, resorted to. Under this treatment the patient's condition rapidly grew worse. On November 26th, 1910, a careful examination was again made. It was found that there was complete loss of sensation to heat and cold, pin pricks, or cotton wool, in the legs and up to the umbilicus in front, and to the 10th rib behind. Above this, for a distance of 10 cm., sensation was blurred, while above the 4th rib in front and the 8th rib behind, sensation was apparently normal. He had a double ankle and rectus clonus. Babinsky and Oppenheim signs were present. The knee jerks are markedly increased and the legs were in a separated condition. The 3rd, 4th, and 5th dorsal vertebræ were not tender to the touch. He had no control over his bladder, and continually complained of pain in the epigastrium and the lower costal borders. He had great difficulty in voluntarily moving his legs.

The question that presented itself was, what was to be done?

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Last May, Professor Lange, of Munich, reported at a meeting of the American Orthopædic Association, at Washington, that eight years ago he had made his first attempt to get fixation of a diseased spinal column by operative procedures. He carried two steel wires, 4 mm. thick, one on each side of the spinal processes, under the muscles, and fastened them with silver wire above and below. These had to be removed in a few months because of the formation of abscesses. They acted as a cause of aseptic suppuration, as does sublimated silk in tendon transplantations. Tin was therefore substituted by Professor Lange,—steel splints carefully covered with tin. Professor Lange's first operation with these tin-coated steel splints was performed two years ago. Since this operation his patient has worked at the anvil in a smithy. The operations performed from that time have been few, but the originator of the operation seemed confident that the procedure was a good one.

The patient, whose condition is being discussed, was rapidly losing ground and becoming paralyzed. Rest by fixation of the spine was the treatment indicated, and yet this seemed impossible by ordinary procedures. It seemed a case, therefore, to try the method suggested by Lange. The spines of the 4th, 5th, 6th, 7th, and 8th dorsal vertebræ were fixed, and I have to report progress towards the betterment of the patient's condition. The wound healed by first intention, and he was sitting up in a chair in less than two weeks after the operation. The condition of his nervous system is also improved. The operation performed on this patient was done about a month before the writing of this report. This history, therefore, is not presented as that of a patient cured of Pott's Disease by operation, but rather as illustrating a procedure both justifiable and to be recommended in certain exceptional cases of tuberculosis of the spine.

A. Mackenzie Forbes.

Montreal.

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pointed artery forceps was inserted and the irregular jagged fragment of bone was withdrawn. There was good use of the ankle-joint. The knee-joint was also unrestricted in movement. The bone on this date seemed firmly knit together and as large over the former gap as the shaft above and below. There was no abnormal mobility. Somewhat more than three months therefore elapsed after bone-grafting before the union was complete, and at that time the gap had been completely filled.

The second skiagram (Fig. 2) was made about June 1. It shows the gap filled with bone. Also, it is interesting to observe that the new-formed shaft which was spindling and weak before the last operation had now become particularly strong toward its lower end, apparently stimulated to overgrowth by the coupling of the two portions by means of the bone-graft.

There is shortening to the extent of three-fourths of an inch. I am unable to say at present whether this is in part on account of injury to the epiphyseal line of growth or entirely because of the action of the muscles not wholly counteracted by the splint-like effect of the fibula. That considerable pressure was put on the fibula is shown by the fact that the upper extremity was forced loose from its joint on the external tuberosity and now occupies a higher position than normal, where it is still movable. There is a backward curvature to the reconstructed tibia, due, I think, to the same inability to control muscle action. There is still a small sinus leading down to necrosed bone, which I believe will be absorbed in time, without the necessity of further operation. Bismuth paste is being injected regularly and there is no suppuration.

The turning up of a bone-flap from the distal portion to fill the gap in the tibia was only the application of the well-known principles of the grafting of the soft tissues. I have no knowledge of a similar case.

I wish to acknowledge the excellent skiagraphs made for me by Dr. A. C. Simon.

NOTE.—At the time of correcting the proof (August 1) the patient is using the leg with no restrictions, and the remaining sinus has closed. The head of the fibula no longer shows abnormal mobility.

TRANSPLANTATION OF A PORTION OF THE TIBIA INTO THE SPINE FOR POTT'S DISEASE

A PRELIMINARY REPORT

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NEW YORK

The following is a final development, from a series of studies, on the application of osteoplasty in the treatment of Pott's disease of the spine.

I was induced to undertake this experimental work on the spine, on account of the excellent operative results obtained in tuberculosis of joints elsewhere in the body where bony union with its perfect support and immobilization has caused the tuberculous process to disappear so rapidly, although only a fractional part of the tuberculous tissues was removed. This has been especially exemplified in my ankylosing operation on the hip, when applied to tuberculous ostitis of that joint, and also in erasion of the knee under similar circumstances. The fact that it is only necessary to secure bony stiffening in tuberculous joints, by operation or otherwise, in order to get a rapid disappearance of the tuberculous process has been emphasized very strongly in the recent writings of Ely, both in his clinical and his pathologic studies. Previous to the herein reported cases, five patients were operated on and three or four spinous processes were split with a chisel or bone forceps for from 1 to 1⅓ inches from their tips, into equal halves, either through a plane approximately parallel with the long axis of the trunk or at right angle to it. The tip of the lower half of the superior vertebra was then brought into approximation with the tip of the superior half of the next lower vertebra after green-stick fractures of each and fastened with heavy kangaroo tendon. Chips of bone from the spinous processes were then placed in between so as to insure further bone union between these vertebræ. Mechanically this event (the union of spinous processes of neighboring vertebræ) acts in two ways: First, if we consider each vertebra a lever (as it properly is) with the fulcrum at the lateral processes, its short arm, the body of the vertebra and the long arm of the lever, the spinous process, then by causing a bony union of the posterior part of the lever, we shall prevent by leverage a crushing together or approximation of the bodies or the anterior arm of the lever.

Nature has done this, i. e., a fusing together of the posterior portions of the vertebræ involved, but unfortunately rarely, as pointed out by Brackett. This prevents absolutely any crushing of the bodies of the vertebræ and thus any further progress of the kyphosis or deformity. Secondly, and possibly not least, this formation of a bony bridge, connecting firmly the diseased vertebræ with the healthy ones on either side, acts directly as an internal splint on the vertebræ involved and furnishes more perfect support than any mechanical apparatus could possibly accomplish.

These assumptions are based, of course, on bony union of vertebra to vertebra as well as union of the green stick fractures of the vertebral halves.

This union has been satisfactory so far as can be ascertained, but on account of its uncertainty and the large amount of cartilage in the vertebræ of small children, with its slowness of union and early lack of support, it has seemed best to devise a procedure which would be possibly more reliable and also give support from the beginning. These requirements can be fulfilled in no other way except by a strong bone-graft.

The different sources from which to secure a strong bone-graft for an internal splint, which would give immediate support to the spine, were considered and the crest of the tibia was selected as by far the most desirable and accessible.

CASE 1.—*History.*—With this in view, R. C., a child aged 4, referred to me by Dr. E. H. Johnston, of Waterbury, Conn., was admitted to the Post-Graduate Hospital.

The past history was negative up to the time the trouble with the spine began. Several months before, the child had begun to have night "cries and sweats," and coincidently began to support herself with her hands on her knees. The mother thought that there had been a loss of weight and that the child was getting pale. There had been pain in the region of the stomach for the past two months. About three weeks before examination, the lump on the child's back was first noticed.

Examination.—This was negative except for a considerable kyphosis at the first and second lumbar vertebræ. The child stooped to pick up things from the floor with difficulty. The spine was rigid to passive and active motion in the region of the kyphosis.

Operation.—The patient was operated on June 9, 1911. Under ether, with the patient in the ventral position, an incision was made, directly over the tips of four spinous processes, with the kyphosis in the center. Each process was then split longitudinally for about one inch and a quarter into two portions with one-third of the process on the left and two-thirds on the right. The soft tissues between the processes were then merely separated by blunt dissection or by a scalpel, parallel

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with the muscles. Green-stick fractures were then produced at the base of the one-third portions of each of the processes. A wedge-shaped cavity was thus produced, ready to receive the bone graft. A compress of hot saline was then placed over the wound. The left leg which had been prepared for operation was then flexed on the thigh, so that an incision over the crest of the tibia anteriorly could be made. A prism-shaped piece of the tibia from its anterior-internal aspect was then removed by means of a chisel, with the periosteum intact on two of its surfaces. The graft taken was about 4 inches by 1 inch, by ½ inch. It was quickly removed and immediately placed in the interval between the portions of the spinous processes. The dense fascia over the tips of the processes was then approximated by interrupted sutures of No. 3 chromic catgut, thus holding the bone-graft very firmly in place. The skin was closed by a continuous suture of No. 1 plain catgut. The leg wound was treated in a similar way. The time of operation was fifteen minutes. There was no shock.

Result.—The child made a fine recovery from the anesthetic. The wounds healed by primary union. The child was discharged from the hospital July 17, 1911. The convalescence has been extremely satisfactory thus far. Muscular spasm of the spinal muscle has diminished very materially. However, it is obvious that it is too early to draw any definite conclusion concerning the final results of any of the cases herein reported, and this is a record of progress only.

CASE 2.—*History.*—The patient, J. M. C., male, was a carpenter, aged 28. His family history was negative to tuberculosis. His present trouble began eight months ago with pain in his back which started in the lumbar region and shot into the thighs. He had night sweats all last winter, but no cough. There was a little pain in his right side when the patient walked and later there was pain in the left side also. There was a mass in the right groin for six months previous to the examination.

Examination.—This was negative except for moderate kyphosis involving the eleventh and twelfth dorsal vertebræ and the right psoas abscess, the size of a fist, just below Poupart's ligament. The spine was very rigid to all motion, both passive and active, in the lower dorsal and lumbar regions. The patient bent the spine with pain and difficulty.

Operation.—June 27, 1911, the Post-Graduate Hospital. Precisely the same operation was done as described in the previous case. The bone-graft from the tibia was much larger, however. It measured about 6 inches by 1⅛ inch by ½ inch. Both wounds healed by primary union. This case was discharged from the hospital July 15, 1911. The patient has gone back to work, wearing a Taylor spinal brace.

CASE 3.—*History.*—The patient, W. D., was a boy aged 4½ years. His past history was negative except for measles and typhoid fever one and two years ago. He began to rest his chin in his hand eight months before examination. There was pain in the neck, which grew progressively worse, and which was complained of at about the same time. A lump on his back was noticed about six months ago.

Examination.—This was negative except for the spinal condition. There was a large angular kyphosis including the last cervical and first two dorsal vertebræ. There was a marked muscular spasm from passive motion. The patient bent with difficulty to pick things from the floor.

Operation.—July 14, 1911, Post-Graduate Hospital. This operation differed from the preceding ones only in reference to the bone-graft. On account of the angularity of the kyphosis, the bone-graft had to be molded into the segment of a circle in order that the corners would not project beyond the tips of the spinous processes distal from the kyphosis. The graft was about 4 inches by 1 inch by ⅜ inch, and included four spinous processes. Both wounds healed by primary union.

This patient is still on a modified Bradford frame. The convalescence has been very satisfactory thus far.

We have at present two cases on reversely bent Bradford frames for the purpose of securing a recession of the kyphosis before operating, and feel confident of holding the correction by the bone-graft.

SUMMARY

1. The inefficiency of present methods in the treatment of dorsal Pott's disease was tersely expressed by Schapps in 1905 as follows: "It is universally admitted that the forms [of portative apparatus] in general use and described in the standard text-books on orthopedics do not, even in the most skilled hands, control the deformity."

2. A firm bony splint with bony union to the vertebra involved and the healthy vertebræ on each side is supplied by this method, which assures not only the prevention of further deformity in two mechanical ways as stated above (leverage and splint action) but should also cause the immediate disappearance of the tuberculous process.

3. This method is believed to be preferable to any, where breaking or cutting of the spinous processes destroys entirely, or for the time being, until union takes place, the desired leverage of the spinous processes and their muscles and ligaments. Union is also uncertain where motion from breathing is present.

4. If bony union should not occur the same mechanical effects would still be largely obtained from the union of the internal bone splint to the ligamentous structures.

5. Perfect immobilization of the few involved vertebræ in the respiratory area of the spine is secured, which is a mechanical impossibility by means of any external apparatus, on account of the constant movement of the ribs, and the vertebræ attached.

6. Fortunately, on account of the anatomy of the part it is not necessary to enter the focus of disease; therefore primary union of soft tissues with immediate bone union can be expected.

7. The normal leverage action of the spinal muscles and the supporting ligaments on spinous processes is not interfered with.

8. The operation is by no means a formidable one. The technic is very simple.

9. When possible it is well to secure a recession of a kyphosis by long recumbency on a reversely bent Bradford frame. This method offers great promise of holding the correction obtained.

10. A bone-graft is far superior to an internal metal splint, because, by following Wolff's law it will become thicker and stronger if necessary to hold the weight or strain brought to bear on it, whereas in the case of an internal metal splint, suture or screw applied to the bone, no dependence can be placed on them to hold weight or strain, because of the bone atrophy and absorption which takes place directly around the metal. This occurs even when no strain is present.

I have found silver wire and screws which were placed through bone only a few months before, in the soft tissues where they had fallen through or out of the bone without being influenced by strain. For this reason and the always present danger of sepsis about buried metal, it would seem that bone-grafting will prove preferable to the internal metal spinal splint of Lange.

125 West Fifty-Eighth Street.

The Structure of Protoplasm.—We are generally agreed at present that it is inaccurate to speak of any one structure as common to all protoplasm, but many cytologists, among whom Bütschli, working chiefly on protozoa, was the first, believe that the different types are referable to one common generalized type which Bütschli described as alveolar in structure. A simple example of such modification of the alveolar into denser plasm can be easily demonstrated in the protruding pseudopodium of *Amœba proteus.*—Calkins in *Science.*

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Interbody, Posterior, and Combined Lumbar Fusions

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Study Design. This is a review article on the different approaches used to obtain fusion of the lumbar spine.

Objective. To describe certain conceptual and technical aspects related to the various fusion techniques that are used commonly for lumbar spine disorders and to discuss the expected clinical results.

Summary of Background Data. There are differences of opinion among surgeons concerning the preferred method for lumbar spine fusion, whether done for deformity, disease, trauma, or degeneration.

Methods. A review of the literature combined with personal experience formed the basis of this article.

Results. At the present time, analysis of the literature does not indicate that one form of fusion is significantly better than another for degenerative conditions of the lumbar spine. There is recent evidence suggesting better outcomes (as distinct from subjective opinion alone) are obtained after anterior interbody fusion than after posterolateral fusion with internal fixation, despite a higher fusion rate in the latter group. There is evidence that suggests late spinal stenosis adjacent to a fusion is more likely to occur with posterior fusion procedures than with anterior fusion alone.

Conclusions. Significant potential complications are associated with all techniques, particularly neurologic damage with posterior interbody fusion, and vascular injury with anterior interbody fusion. Spinal fusion procedures should only be done by surgeons with the necessary training and expertise. [Key words: combined fusions, interbody fusion, posterior fusion] **Spine 1995; 20:167S–177S**

Since the first reports of spinal arthrodesis 84 years ago,[2,35] a variety of techniques for fusion in the lumbar spine have been developed for the management of a wide range of conditions. Reported success rates for each technique have varied considerably, and there are no published studies comparing one method of fusion with another. Although it is accepted that the approach should be determined by the abnormal condition being treated, most procedures are performed for low back pain, the etiology of which remains controversial. This paper is directed at an appraisal of the application of interbody, posterior, and combined fusions for lumbar spine disorders.

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Conceptual Aspects

General

The literature contains relatively few descriptions of the exact rationale for fusion of the lumbar spine. Arthrodesis of the lumbar spine has been used to prevent or correct deformity, for the eradication of disease, to stabilize the spine after trauma or abnormal destruction, and to eliminate the movement of painful segments. It is the management of a painful motion segment by spinal fusion that generates the most controversy and to which most of this paper is devoted.

Deformity

The concept of spinal fusion is generally attributed to Hibbs[35] and Albee,[2] who devised posterior fusion techniques to control the progressive kyphosis associated with tuberculosis. A few years later, Hibbs[36] applied his fusion technique to the treatment of scoliosis, the principle being to arrest progression of the curve. Today the concept of fusion in the treatment of lumbar spinal deformity is to maintain a position that has been reduced or corrected by internal fixation with or without traction or bracing. As the emphasis is on correction of the deformity by internal fixation, the choice of anterior or posterior fusion techniques is usually dictated by which form of fixation coupled with release of soft tissue or an osteotomy will best enable correction of the deformity. The management of complex spinal deformities, including paralytic scoliosis,[65] iatrogenic flat back deformity,[49,54] lumbar kyphosis from trauma,[47] and severe spondylolisthesis and spondyloptosis,[7,59] led to the concept of combining anterior interbody fusion with posterior arthrodesis. The combined approach was developed with the aim of enabling easier and greater correction with more scope for obtaining adequate neural decompression. In such patients, a combined fusion is thought to minimize the risk of pseudarthrosis, particularly at the lumbosacral junction in cases of multiple level fusion.

Eradication of Disease

The surgical management of destructive infectious and neoplastic diseases best illustrates the principle of choosing an approach appropriate to the abnormal condition. It was Hodgson[37] who pioneered the anterior approach for spinal tuberculosis. As nearly all tuberculous and

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nontuberculous infections of the spine involve the disc and endplates, anterior disc clearance and interbody fusion is the procedure of choice when surgery is required. The rationale of fusion in such cases is not only to prevent deformity and restore stability but also to reduce the risk of recurrence of infection by removing necrotic tissue and obliterating the disc space. Spinal fusion often plays a major role in the surgical management of primary and metastatic neoplasms,[50] the preferred approach depending on the location of the disease. When there is extensive destruction, circumferential fusion combined with internal fixation may be required to obtain stability. Although such a combined approach represents a greater surgical insult, this has to be balanced against the advantages of rapid mobilization and shorter hospital stay, which may be of prime importance to a patient with a shortened life expectancy.

Instability

The term "instability" is best reserved for traumatic or destructive lesions where there is major disruption to spinal integrity causing significant loss of function. Abnormal conditions, such as infection and neoplasm, may cause such destruction, but the most common cause is trauma. The rationale of fusion in these cases is to restore the structural integrity of the spine.

In traumatic lesions, surgical management aims at restoring anatomical alignment and reducing neural compromise, whereas the role of fusion is to reduce the risk of loss of correction and to reduce long-term symptoms from the movement of painful joints. Often the approach is determined by the site of neural compression, an anterior approach being favored by some where there is significant retropulsion of vertebral body fragments into the spinal canal.[44] In such instances where adequate internal fixation cannot be obtained anteriorly, there may be justification for a simultaneous posterior approach.[48] Although fusion is considered a necessary adjunct in such cases, similar results have been reported after the surgical management of unstable lumbar injuries managed by open reduction and internal fixation without the addition of fusion.[67]

A less severe form of structural instability, but often just as disabling, occurs when the integrity of the pars or facet joint is destroyed during laminectomy, particularly in cases of degenerative spondylolisthesis and multiple laminectomy. Logically, when apparent at the time of the primary procedure, iatrogenic instability is best managed by a "prophylactic fusion." Because this is more likely to occur in an older age group and at the time of a posterior decompression, an intertransverse fusion is the most common method used.

Painful Motion Segment

The major area of controversy undoubtedly concerns the broader concepts of "segmental instability" and "discogenic pain" and the widespread use of fusion in this regard. Clinical instability has been described in detail by a number of authors including Kirkaldy-Willis.[46] This same author has been unable to correlate specific symptoms and signs with a specific type of radiologic instability.[16] As Frymoyer[25] states "much has been speculated about the clinical signs and symptoms of instability, but only minimal reliable and reproducible clinical information is available." The literature contains many definitions of lumbar instability centered around pain produced by abnormal segmental motion. The term as such does not indicate the exact pain source, which according to the breadth of most definitions, may reside in the disc, facet joints, ligaments, or other soft tissues. Various tests have been used with the aim of localizing the patient's pain source before a fusion, principally pain provocation by discography, and pain abolition by facet blocks[70] or external fixation.[42,66] There has been considerable controversy over the reliability and usefulness of such investigations.[61,63]

The most common fusion technique used for the surgical treatment of segmental instability has been the posterolateral fusion. The proponents of this technique consider that the graft is sufficiently near the center of vertebral rotation to prevent movement of pain-sensitive tissue, whether this involves anterior or posterior structures.

In general, those authors favoring an interbody fusion consider the disc to be the prime source of the patient's symptoms, referring to such entities as discogenic pain, internal disc disruption,[14] and symptomatic anular tears. Disc clearance and interbody fusion has the theoretic advantage of removing a discogenic pain source and obliterating movement.

In recent years, combined interbody and posterior fusion has been advocated for the management of discogenic pain, particularly after failed laminectomy, for multiple level procedures, and for large patients. Advocates of this approach cite the advantage of removing all potential sources of spinal joint pain and obtaining higher rates of fusion. The stimulus for this approach seems to have come from the finding that discogenic pain may not be relieved by a well-consolidated posterior or posterolateral fusion, but it can subsequently respond to anterior disc clearance and interbody fusion.[79]

The concept of a painful motion segment is accepted generally as appropriate for cases of disabling back pain associated with lytic and degenerative spondylolisthesis, both considered by many authors to be examples of "instability." In such cases, arthrodesis is aimed at preventing the anteroposterior or rotational movement thought to be responsible for producing pain, and the procedure may be combined with internal fixation to restore alignment and enhance fusion.

Although common in the community and usually asymptomatic, spondylolysis has been associated with disabling back symptoms. The source of pain in many cases is considered to originate from the defect itself, as evidenced by the strong association between symptom

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relief by pars defect blocks[74] and a successful outcome from fusion. In this condition, fusion may be limited to a direct repair,[9,60,62,69] which aims to relieve pain by removing the pain source and by restoring bony anatomy.

Disc Herniation

There is little evidence to support the routine use of spinal fusion combined with disc fragment excision for radicular symptoms from lumbar disc herniation.[75] Spinal fusion may be combined with disc excision in cases of recurrent disc herniation to minimize or prevent a further occurrence or where long-standing disabling back pain is the major symptom. There is a theoretic advantage of posterior lumbar interbody fusion (PLIF) in this regard because of the ability to perform the operation combined with neural decompression, but this must be balanced against the neurologic risks associated with retraction of a scarred and adherent thecal sac. As with anterior interbody fusion, the PLIF technique, first performed by Cloward[11] in 1943, has the following claimed advantages: the graft material is under compression; the disc space can be distracted, decompressing the neural foramina; and the pain source is removed.

Technical Considerations

General Considerations

The most important aspects to the attainment of a solid arthrodesis are meticulous preparation of the graft bed and accurate placement of an adequate amount of good quality bone graft material.

Posterior Fusions

Posterior Midline Fusions. In 1911, Hibbs[35] and Albee[2] described different techniques for posterior arthrodesis of the spine, which they applied to the management of dorsal and dorsolumbar tuberculosis. The technique described by Hibbs, often with modifications, became the preferred method of fusion for lumbar spine disorders over the next 5 decades. In the original description by Hibbs, small strips of bone were elevated from the spinous processes and laminae, as part of the process of decortication. Later, autologous bone graft was added either as additional strips or as a "clothespin" construct.[5] In the 1960s, posterior arthrodesis of the lumbar spine was largely abandoned after claims that it led to laminal hypertrophy causing underlying spinal stenosis.[58] In addition, the technique was associated with a higher rate of pseudarthrosis than with the other methods of fusion in use at that time.

As an isolated technique, posterior midline fusion has a number of disadvantages: the graft material is situated at a distance from the center of vertebral rotation and placed under tension leading to higher rates of pseudarthrosis, and future access to the spinal canal is impeded. It does have the advantage that the procedure can be performed without the need for such an extensive exposure as required for posterolateral fusion, sparing muscle damage beyond the site of fusion. Except for pain that may originate from posterior midline tissues, the rationale for this technique for the management of spinal pain relies entirely on its potential for reducing load through other more likely pain-sensitive structures, particularly the intervertebral disc and facet joint.

Facet Joint Fusion. Fusion of the facet joint is considered by most authors to be an important component of the more commonly used posterolateral fusion and the posterior midline fusion. Isolated arthrodesis of the facet joint, often promoted in the past, is used less commonly today. Methods of isolated facet joint fusion included the use of internal fixation with screws[6] and mortice in-lay techniques, using either blocks or dowels. In keeping with his torsional theory of instability,[18] Farfan described a facet fusion technique for derotating and fusing motion segments.[20] Isolated facet joint fusion is in theory appropriate for the management of facet joint pain, but it has the major disadvantage of a limited area of bony contact for graft incorporation.

Posterolateral Fusion. The technique of fusion of the facet joints, partes interarticulares, and bases of the transverse processes was first described by Watkins in 1953[78] and later modified by Wiltse[80,81] who included the laminae in his fusion technique. Since that time, posterolateral lumbar fusion has remained the most commonly used method of arthrodesis (Figure 1). When the bilateral sacrospinalis muscle-splitting approach[82] advocated by Wiltse is used, the access for doing the procedure is greatly improved, blood loss is reduced, there is easier and safer access for pedicle screw insertion, and autologous bone graft can more readily be obtained, with less risk of a painful donor site. The additional disadvantage to doing a posterolateral fusion through a midline approach is the extra length of the wound required to gain an equivalent exposure, resulting in more extensive damage to the muscles protecting the adjacent motion segments. This may have adverse long-term effects related to the development of juxtafusion degeneration. When laminectomy is required as an adjunct to a posterolateral fusion, combined midline and posterolateral approaches[23] can be used to gain optimum exposures for the two separate components of the operation, or in some situations laminectomy through the Wiltse approach may give sufficient access.[83] These advantages over the midline approach do not apply for procedures on the more superficial upper lumbar spine.

The main claimed advantage with the intertransverse fusion compared with the posterior fusion is a reduced rate of pseudarthrosis, resulting from a greater vascular supply for the graft bed and from placement of the arthrodesis close to the center of vertebral rotation.[58] Because of continuing minor movement through the pedicles, a discogenic pain source is believed to persist in some patients with a solid intertransverse fusion,[79] par-

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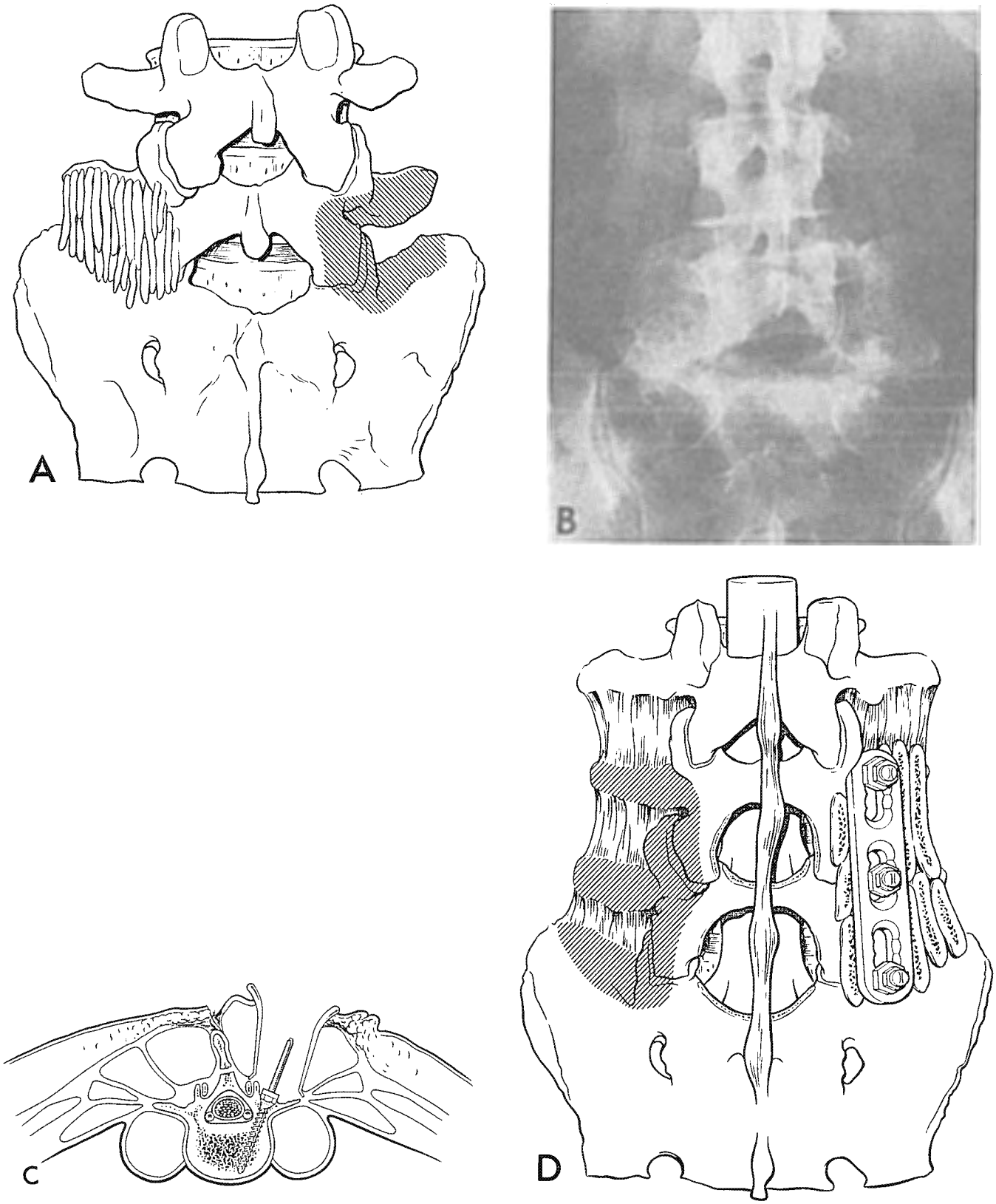

Figure 1. Posterolateral fusion. (**A**) A technique of posterolateral (alar transverse) fusion. The hatched area represents the extent of decortication. (**B**) Anteroposterior radiograph of lumbosacral spine showing a solid alar transverse fusion. (**C**) A diagram to show how placement of a pedicle screw is facilitated by the Wiltse paraspinal muscle-splitting approach (From Fraser and Hall[23]). (**D**) A posterior view showing the area to be decorticated (hatched area) for L4–S1 posterolateral fusion and the final appearance after graft placement with plate and pedicle screw fixation (From Fraser and Hall[23]).

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ticularly when the facet joints are not included in the arthrodesis. For similar reasons, a consolidated but tenuous intertransverse fusion alone may fail to control symptoms originating from the facet joints.

Although graft material may be wedged within the facet joint, most of the bone in a posterolateral fusion lies free, being placed over and between the decorticated transverse processes, partes interarticulares, facet joints and, laminae (Figure 1). Unless the graft is held down by a spinal plate, it is the repositioning of the paraspinal muscles that is given the responsibility of preventing graft displacement. Migration of a posterolateral fusion mass may result in a painful pseudarthrosis developing at an adjacent level.

Whether the Wiltse muscle-splitting approach or the midline muscle stripping approach is used, a posterolateral fusion carries the distinct disadvantage of causing damage to important stabilizing muscles and damage to the nerve supply of these muscles, in itself a possible mechanism for continuing pain and loss of function. Graft displacement[23] has been described as a cause of impairment of nerve root function. In some circumstances (*e.g.*, after posterolateral decompression for a "far-out syndrome" in a patient with lytic spondylolisthesis), it may be necessary for the posterolateral fusion technique to be used on one side alone.[33]

Interbody Fusions

Anterior Interbody Fusion. It is generally agreed that the technique of anterior interbody fusion is particularly applicable to abnormal conditions involving the anterior or middle column, after posterior surgical procedures have failed, and when the motion segments being fused are kyphotic. The application of anterior disc clearance and interbody fusion to chronic low back pain is inextricably linked with the acceptance of discogenic pain as an entity.

Most authors advocate a retroperitoneal approach, except for cases where there is difficult access to the lumbosacral junction, such as spondylolisthesis of more than 25% when a transperitoneal approach is usually preferred.

To minimize damage to the abdominal muscles—important for their protective action against rotational forces—a muscle-splitting rather than muscle-cutting approach is desirable.[21,22] The key to exposure of the lumbosacral and low lumbar intervertebral discs rests with adequate mobilization and retraction of the iliac vessels (Figure 2), and without this being achieved, preparation of the endplates and placement of the grafts are likely to be inadequate. It is the risk of damage to the iliac vessels, occurring in up to 18% of patients in one series,[3] which presents the greatest challenge during the exposure. Surgeons using this technique need either to be trained in the exposure or should seek the assistance of a vascular surgeon. The earlier concerns of impotence from damage to the presacral plexus were unfounded. Injury to this plexus in men results in retrograde ejaculation and sterility, not impotence.[15,43] With careful technique there is a small risk of retrograde ejaculation in men with exposure at L5–S1, mainly when the transperitoneal approach is used. A large number of different techniques for graft insertion have been described, generally fitting into one of three categories: corticocancellous blocks,[38] corticocancellous dowels[13] (Figure 2), and cancellous chips or milled bone tightly packed into a supporting "cage," such as Titanium mesh, femoral cortical ring allograft,[39,51,53] carbon fiber implants,[8] or perforated Titanium dowels. The advantage of the dowel techniques is the capacity consistently to obtain accurate fitting of the graft or "cage" to the prepared graft bed. The disadvantage with these techniques is that the strong trabeculae adjacent to the endplates are breached, increasing the risk of graft settling. The advantages of corticocancellous blocks are the potential for preserving much of the endplate and of filling the disc space with a greater quantity of bone graft, factors that should reduce the risk of graft collapse and increase the fusion rate. The accurate insertion of individual blocks is less reproducible than with the dowel techniques. The use of "cages" carries the added advantage of minimizing problems associated with the harvesting of large amounts of corticocancellous bone from the iliac crest.

Anterior interbody fusion requires removal of a significant portion of the anterior anulus and anterior longitudinal ligament or anterolateral anulus and relies on tension in the remaining anulus for inherent strength of the construct. The approach enables wide disc clearance to be achieved with removal of the posterior anulus and longitudinal ligament if removal of bone or disc fragments from the anterior spinal canal is required.

Although there are a number of methods for combining the approach with internal fixation in the upper and mid lumbar spine, the course of the iliac vessels prevents satisfactory anterior internal fixation from L4 to the sacrum. Exposure of L4–L5 in particular requires retraction and often partial and sometimes complete division of the sympathetic chain, which may produce long-term, although usually minimal, lower limb symptoms.

Posterior Interbody Fusion. This procedure shares similar choices of graft and "cage" techniques and most of the advantages and risks associated with anterior interbody fusion. Although the risk of damage to retroperitoneal structures should be minimal, iliac vessel damage is a potential hazard. The procedure is not appropriate for the management of some anterior column diseases, such as infection, but has the advantage over the anterior approach of enabling abnormality within the entire spinal canal to be dealt with through the one approach. In experienced hands, the risks associated with the necessary retraction of the cauda equina and nerve roots to do the procedure would appear to be acceptable, but unfortunately there is a steep "learning curve"[57] with cauda equina lesions occurring in one series[76] in 19% of cases (four of 21 patients, of whom three did not recov-

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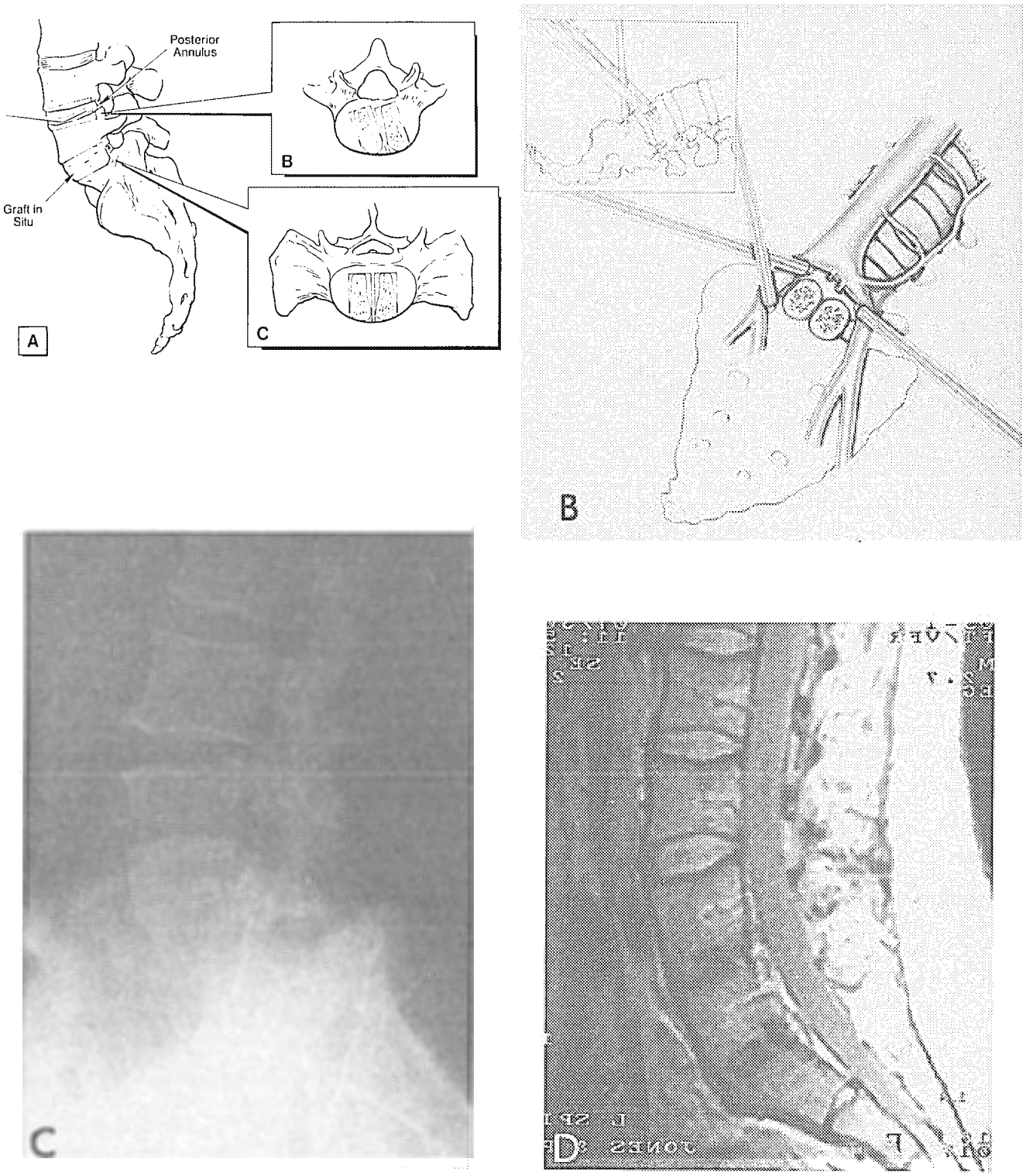

Figure 2. Anterior interbody fusion. (**A**) The dowel technique of anterior interbody fusion at L4–L5 and L5–S1 as described by Crock.[13] (**B**) The use of Steinman pins to retract the common iliac veins during anterior interbody fusion at L5–S1 (From Fraser[22]). (**C**) A lateral radiograph of the lumbosacral spine 11 years after anterior interbody fusion at L4–L5 and L5–S1. (**D**) A sagittal T2-weighted magnetic resonance image of the lumbosacral spine in the same patient 11 years after surgery showing essentially normal discs in the lumbar spine above the fusion.

er). This disastrous complication reflects the degree of thecal sac retraction required during the insertion of either corticocancellous grafts or cages containing bone graft. The spinal canal simply is not large enough to permit the safe passage of this material without removal of large portions of the facet joints. In addition to the obvious potential for operative neurologic damage, disadvantages include the development of extensive epidural fibrosis and the neurologic effects of posterior graft displacement.

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Combined Fusions

It is because of the significant drop in the fusion rate over multiple levels that a number of surgeons have combined interbody fusion with posterior fusion and usually internal fixation. The combination of anterior interbody fusion with a posterior fusion technique was developed initially for the management of complex lumbar spine disorders and has been applied to the management of chronic back pain with the aim of obtaining higher rates of fusion and improved outcome. Although some surgeons prefer to do the procedures a week apart, the operation is most commonly done in two stages on the one occasion.[52,64,71] The technique for combined anterior and posterior fusion for degenerative disorders usually involves posterior internal fixation with distraction rods, translaminar screws, or pedicle screw fixation systems[52,71] (Figure 3). Increased fusion rates are reported with the technique even for single-level disorders.[45] The fusion rate still falls for procedures beyond two levels.[52] For the management of destructive lesions and for the correction of deformity involving the middle and upper lumber spine, the procedure is often combined with anterior internal fixation.[44]

Some authors favor fusion of the anterior and posterior spinal columns through a posterior approach alone;[17] a posterior interbody technique is combined with intertransverse grafting usually with the addition of pedicle screw fixation. To increase exposure and reduce the risks of dural traction and to enhance correction of deformity, the combined fusion technique described by Steffee[17] includes removal of the facet joints and the partes interarticulares (Figure 3A). This, together with the subsequent removal of much of the intervertebral disc, leads to high demands on the strength of the graft construct and internal fixation device. The extent of bone removal limits the posterolateral bony bed available for grafting.

Combined fusions have potential disadvantages related to the increased magnitude of the procedure. The claimed advantages of high fusion rates and improved outcome must be balanced against the increased risk of morbidity.

Expected Clinical Results

The literature contains numerous reports of experience with the various lumbar fusion techniques described. Reported success rates for clinical outcome and for fusion rates vary considerably. Part of this can be explained by the wide differences between reports of what constitutes a successful outcome. Comparison of 14 outcome measures[40] revealed that the proportion of "successes" varied according to the outcome measure used, ranging from 60% to 97%. Subjective measures, *e.g.*, the patient's opinion of the operation, gave a higher proportion of "successful" results when compared with objective measures, such as return to original employment. Likewise, the rates of arthrodesis depend to a great extent on investigator interpretation. Much higher rates of fusion are claimed when the loss of movement on lateral flexion and extension views is the sole criterion for arthrodesis[12] than in reports where presence of continuous trabeculae across the graft vertebra interface is the main determinant,[10,72] providing up to a 20% difference in fusion rate.[53] To date, there have been no randomized controlled studies comparing one fusion technique with another, and because influences such as compensation[27] and psychologic disturbance[28] have been shown to have such a profound effect on outcome and in one study even on the fusion rate,[30] it is difficult and probably unreliable to draw many conclusions from the available literature.

Recently, an analysis was made of selected articles published in English language journals from 1966 to 1991.[75] Only 47 articles were considered to fulfill the selection criteria: a minimum 1-year follow-up period with data permitting the classification of clinical outcomes as satisfactory or unsatisfactory for at least 30 patients. Of the 47 articles selected on this basis, none reported randomized trials and none compared different methods of spinal fusion. The data accumulated from these studies showed no significant differences in satisfactory clinical outcomes according to type of fusion, classified as posterior, posterolateral, anterior interbody, and posterior interbody. Although there was a significant difference in the rates of arthrodesis obtained by anterior and posterior interbody fusion, this was probably because of differences in interpretation. The radiologic criterion in two of the four papers[12,41] describing posterior interbody fusion was lack of movement on lateral flexion and extension views, with one paper[12] including patients with "sound fibrous union" (11%) in the fusion rate of 97%. Of particular importance was the lack of an association between pseudarthrosis and symptoms in individual patients.[75] The view that discogenic pain can be relieved by incomplete stiffening of the painful motion segment is supported by the findings of a number of authors, who have found no association between the attainment of a solid fusion and clinical outcome,[1,19,24,31] except for lytic spondylolisthesis.[1,34]

In a recent but as yet not fully published study,[32] an independent review of a comparative series of anterior interbody fusions[31] and posterolateral fusions with pedicle screw and plate fixation has been done. All procedures were performed by one surgeon, and there was a minimum follow-up period of 2 years. Although the fusion rate for anterior interbody fusion was less than that for posterolateral fusion with internal fixation, there was no difference in the subjective opinion of fusion between the two groups. There was a difference in assessment of outcome by the more objective Low Back Outcome Score,[29,30] with patients treated by anterior interbody fusion gaining significantly better results for compensation and noncompensation patients. The improved outcome in the anterior fusion group, despite the higher pseudarthrosis rate, supports the con-

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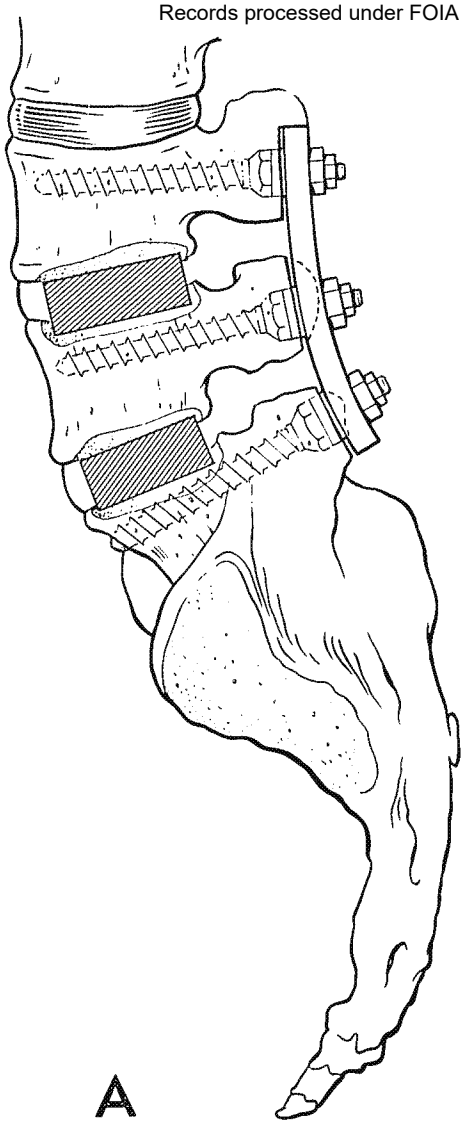

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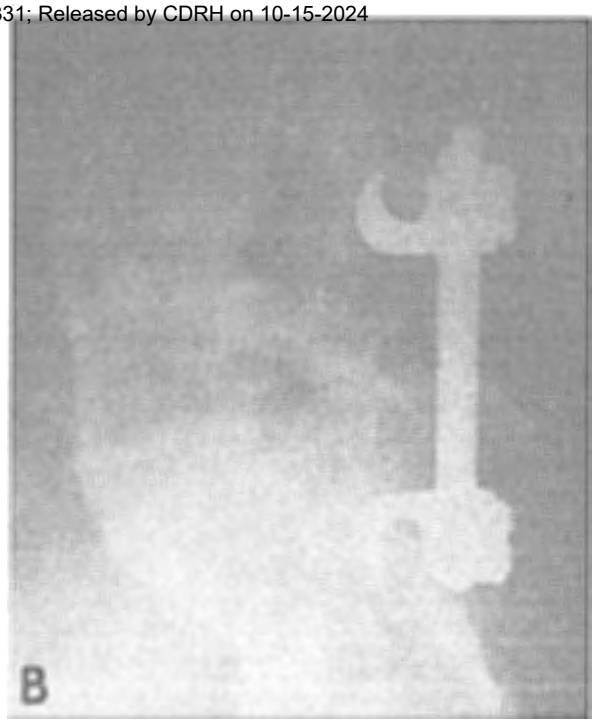

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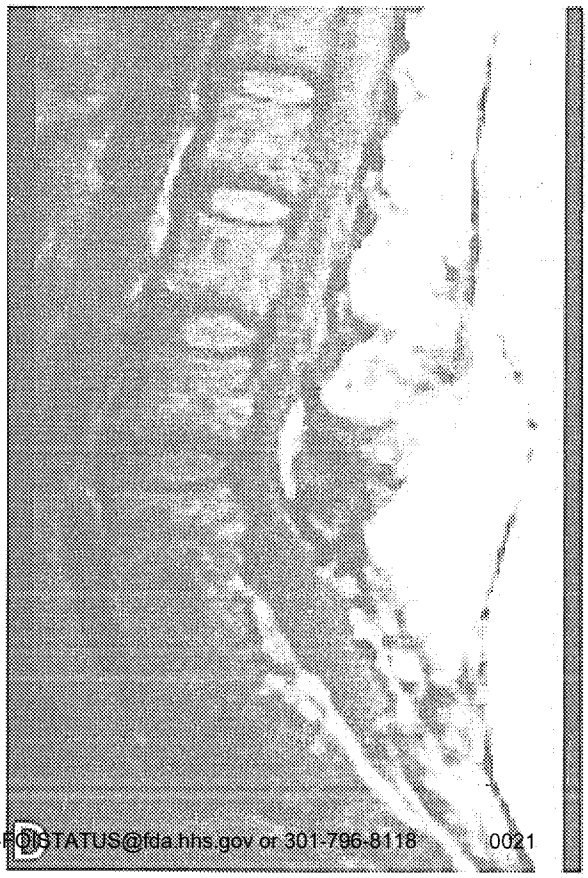

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Figure 3. Combined fusions. (**A**) Posterior interbody graft placement when combined with pedicle screw and plate fixation as described by Steffee.[33] (**B**) Lateral radiograph of lumbosacral spine 2 years after anterior interbody fusion at L4–L5 and L5–S1 combined with posterior distraction rods and facet fusion. (**C**) Lateral radiograph of lumbosacral spine 12 years after combined anterior interbody and posterolateral fusion from L4 to the sacrum. (**D**) A sagittal T2-weighted magnetic resonance image in the same patient as Figure 3C (12 years after surgery). Degeneration of the L3–L4 disc is evident with hypertrophy of the L3–L4 apophyseal joints resulting in spinal stenosis.

cept that part of the benefit with anterior fusion is removal of the pain source itself. Another possible explanation is that some of the patients' continuing pain and disability is related to the effects of posterior surgery on the spinal musculature and the presence of a rigid pedicle screw fixation system.

The possible effects of the surgical interference to the spinal musculature and of the fusion itself in the long term is of concern. There is little information in the literature on the influence of these factors on the development of adjacent degeneration. Lehman et al[55] in a study of 33 patients treated by posterior midline fusion reported a 30% incidence of spinal stenosis above the fusion site after a minimum follow-up period of 21 years. The exact preoperative state of the discs above the fusion was not known. There are conflicting reports on the incidence of degeneration above a fusion after 10 years. Frymoyer et al[26] reported "disc disease" on radiographs above the level of posterior and posterolateral fusion in only 5% of patients. Leong et al[56] found disc degeneration adjacent to an anterior fusion in more than 50% of patients treated for disc prolapse, a condition itself associated with a high incidence of adjacent degeneration. The preoperative state of adjacent discs was not assessed by discography. In contrast to this, Van Horn et al[77] found an incidence of radiographic degenerative changes of the adjacent discs 16 years after anterior spinal fusion similar to that in a matched controlled population. Recently, Penta et al[68] reported the incidence of disc degeneration determined by magnetic resonance imaging 10 years after anterior lumbar interbody fusion. Where the adjacent intervertebral disc was normal on discography before surgery, the magnetic resonance image of the disc remained normal 10 years later in 68% of patients, and the pattern of degeneration in the unfused segments of the lumbar spine was similar to that reported in asymptomatic individuals,[4] supporting the view that lumbar anterior fusion has little influence on the development of adjacent degeneration (Figures 2C, 2D). The incidence of significant spinal stenosis developing above an anterior spinal fusion for all patients was found to be only 2.5% compared with 30% for the posterior fusion group reported by Lehman et al.[55] The differences in follow-up periods makes a comparison unreliable, but this trend and the results of the recent comparative study[32] suggest anterior fusion has advantages over posterior fusion procedures in the long term. Although combined fusion procedures may have significant benefits in the short term, the added posterior rigidity and the additional damage to the supporting musculature could lead to an increased incidence of symptomatic degeneration and stenosis at the adjacent levels (Figures 3C, 3D).

As the fusion techniques described are frequently combined with internal fixation, the effects of alteration of spinal alignment need to be addressed. The experience with long fusions for degenerative lumbar scoliosis has highlighted the potential for marked acceleration of adjacent degeneration when the spine is not in balance.[17] Although fusion of the spine in an anatomic position would seem not to exacerbate the degenerative process in an adjacent normal disc, the same is not necessarily the case with an adjacent degenerate disc, particularly when the spine is not in balance or when the normal curves have been significantly altered through instrumentation.

Conclusions

The present article has addressed certain conceptual and technical aspects related to the various fusion techniques that are used commonly for lumbar spine disorders. At the present time, analysis of the literature does not indicate that one form of fusion is significantly better than another for degenerative conditions of the lumbar spine, and there is a need for randomized controlled trials to assess this issue.

There is recent evidence from a comparative retrospective study that better outcomes (as distinct from subjective opinion alone) are obtained after anterior interbody fusion than after posterolateral fusion with internal fixation, despite a higher fusion rate in the latter group. There is evidence to suggest that late spinal stenosis adjacent to a fusion is more likely to occur with posterior fusion procedures than with anterior fusion alone. Significant potential complications are associated with all techniques, particularly that of posterior interbody fusion, and spinal fusion procedures should only be done by surgeons with the necessary training and expertise. Finally, the principle of choosing the appropriate procedure according to the abnormality being treated should remain. The problem is that for chronic low back pain there is no general agreement on what is the relevant pathology.

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HEALTH SERVICES RESEARCH

Trends in Utilization and Cost of Cervical Spine Surgery Using the National Inpatient Sample Database, 2001 to 2013

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Study Design. A retrospective review.

Objective. The aim of this study was to determine national rates of cervical spine surgery and to examine factors that underlie cost variation.

Summary of Background Data. There has been an increase in the rate and cost of spinal surgery over the past decades, but there is little understanding of the drivers of cost variation at the national level.

Methods. We analyzed 419,830 patients who underwent cervical spine surgery (anterior cervical fusion, posterior cervical fusion, posterior cervical decompression, combined anterior/posterior cervical fusion) for degenerative conditions in the 2001 to 2013 NIS database. We determined the rates of surgery by time and geographic region, and then created univariate and multivariate models to evaluate the effect of these factors on total hospital costs: patient age, gender, race, insurance, income, county of residence, elective *versus* nonelective case, length of stay, risk of mortality, severity of illness, hospital bed size, wage index, hospital type, and geographic region.

Results. The most common type of cervical spine surgery was anterior fusion (80.6% of all surgeries). The national rates of all cervical spine surgery decreased slightly from 2001 to 2013 (75.34 to 72.20 per 100,000 adults), while the mean inflation-adjusted cost increased 64%, from $11,799 to $19,379, during this time period. Multivariate analyses showed that older age, male gender, black/other race, private insurance, greater risk of mortality/severity of illness, and longer length of stay were associated with higher costs. The wage index was positively correlated with cost, and hospitals in the western U.S. were 27% more expensive than those in the Northeast.

Conclusion. The rate of cervical spine surgery decreased slightly, while the mean case cost increased at a rate double that of inflation from 2001 to 2013. Even after controlling for patient and hospital factors including wage index, there was significant geographic variation in the cost for cervical spine surgery.

Key words: anterior cervical discectomy and fusion, anterior-posterior cervical fusion, cervical spine surgery, cost variation, national inpatient sample (NIS) database, posterior cervical decompression, posterior cervical fusion, rate of surgery, surgical cost, surgical utilization.

Level of Evidence: 3

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Medical costs in the United States are the highest in the world, where we spent $8713 per capita on health care in 2012.[1] Within this expensive health care climate, spine surgeries are common and among the most costly procedures.[2]

A growing body of evidence reveals a substantial increase in the rate of spine surgery over the last 30 years.[3–7] Between 1992 and 2005, the rate of cervical spine procedures among Medicare beneficiaries tripled.[4] The increase in frequency of surgery has been coupled with a concomitant increase in cost per surgery. Total hospital costs for an episode of cervical spine surgery increased 48% between 2002 and 2010.[8] There

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is significant geographic variation in cervical spine procedure frequency[4] and cost,[9] which mirrors findings for lumbar spine surgery[3,9,10] and total joint arthroplasty.[11]

Multiple factors may contribute to variation in cost for cervical spine surgery, including specific procedure type, age, race, comorbidities, hospital teaching status, and hospital case volume. The goal of our study is to examine the utilization rates of different types of cervical spine surgery [anterior cervical fusion (ACF), posterior cervical fusion (PCF), posterior cervical decompression (PCD), combined anterior-posterior surgery] and to determine the factors underlying cost variation in cervical spine surgeries from 2001 to 2013 using the National Inpatient Sample (NIS) database.

MATERIALS AND METHODS

We analyzed patients ≥18 years old who underwent cervical spine surgery for degenerative disease from 2001 to 2013 in the Healthcare Cost and Utilization Project (HCUP) NIS database. Patients undergoing cervical spine surgery were identified with the following ICD-9-CM procedure codes: ACF (81.02), PCF (81.03), and PCD without fusion (03.09 in absence of fusion codes 81.02 or 81.03), and combined anterior-posterior cervical fusion (APCF, 81.02 and 81.03). We identified patients undergoing surgery for degenerative disease using the following ICD-9-CM diagnosis codes: 721.0-1, 722.0, 722.4, 722.71, 722.81, 722.91, and 723.x, as defined by Oglesby *et al.*[7] and Marquez-Lara *et al.*[8]

On the basis of these criteria, we identified 419,830 patients who underwent cervical spine surgery for degenerative conditions in the NIS database from 2001 to 2013. The following variables were collected for each case: patient age, gender, race, insurance type, mean annual income of patient's zipcode (<$39,000; $39,000–47,999; $48,000–62,999; >$63,000), description of patient's county of residence (central metropolitan county with population >1 million, fringe county of metro area>1 million population, county in metro area 250–999k population, county in metro area 50–249k population, micropolitan county <50k population, not metropolitan or micropolitan county), elective *vs.* nonelective case, length of stay (LOS), All Patient Refined Disease Related Group (APR DRG) risk of mortality (minor, moderate, major, extreme), APR DRG severity of illness (minor, moderate, major, extreme), hospital region (Northeast, Midwest, South, East), hospital location (rural, urban non-teaching, urban teaching), hospital bed-size (small, medium, large), and year-specific wage index. Hospital bed-size in the NIS is based on the total number of hospital beds and is specific to the hospital's location, region, and teaching status. APR-DRG severity of illness is defined as the extent of physiologic decompensation or organ system loss of function. Both the APR-DRG severity of illness and risk of mortality are calculated using a proprietary formula from the principal and secondary diagnoses, procedure codes, age, sex, and discharge disposition of the patient. For example, a minor severity of illness (SOI) would be uncomplicated diabetes, moderate is diabetes with renal manifestations, major is diabetes with ketoacidosis, and extreme SOI is diabetes with hyperosmolar coma.

We calculated the hospital costs for each case by multiplying hospital charges and the unique all-payer inpatient, year-specific cost-to-charge ratio of the corresponding hospital. Costs were then adjusted for inflation (*i.e.*, all costs were expressed in 2013 dollars) using the U.S. Consumer Price Index rates.[12]

We collected and sorted data in Stata 13 (StataCorp, College Station, TX), and performed statistical analyses in R Foundation is a free online Statistical Package (v 3.2.3; https://www.r-project.org/about.html). To analytically handle the complex design of the NIS, we applied the Agency for Healthcare Research and Quality's survey package in R. We performed univariate and then multivariate survey-weighted least squares regression (general linear model) to evaluate the effect of each patient and hospital variable on total cost for cervical spine surgery. We used the gamma distribution for the general linear model because cost is a right-skewed positive continuous variable. Our multivariate model was multiplicative because a logistic link function was used, meaning that coefficients should be interpreted as percent changes in cost: for example, a coefficient of 1.05 shows that this category is 5% more expensive than the reference category.

RESULTS

Table 1 summarizes the patient and hospital characteristics of 419,830 patients who underwent cervical spine surgery for degenerative conditions in the NIS database from 2001 to 2013. The most common type of surgery performed was ACF alone, which accounted for 80.6% of cases (n = 338,177); only 2% of patients (n = 8005) underwent both anterior and posterior cervical fusion (APCF; Table 1). Across all types of cervical spine surgery, the average age of the patients was 53.7 ± 12.4 years. Patients undergoing ACF were younger (52.26 ± 11.75 yrs) than those undergoing PCF (mean age = 60.76 ± 12.59 yrs) or PCD alone (mean age = 59.46 ± 13.31 yrs). About 49.7% of all cervical spine surgery patients were male, with higher rates of males undergoing posterior cervical procedures (57.1% males had PCF *vs.* 47% males in ACF group; Table 1).

Across all types of cervical spine surgery, the majority of patients were white (64.3%). Numbers of different types of cervical spine procedures (ACF, PCF, PCD, ACPF) were similar across races (Table 1). About 55.2% of patients undergoing all types of cervical spine surgery had private insurance. There were higher numbers of ACF in patients with private insurance than those with Medicare (Table 1). Most patients had either minor/moderate risk of mortality or minor/moderate severity of illness, and mean LOS was 2.5 ± 4.1 days across all cervical spine surgeries. LOS was lowest for ACF (1.96 ± 3 days, and highest for combined anterior-posterior fusions (7.51 ± 9.15 days). The number of comorbidities was also higher in the group of patients who underwent APCF (5.4 ± 2.94 days), than those who underwent ACF alone (3.75 ± 2.41 days). The majority of

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TABLE 1. Patient and Hospital Characteristics for 419,830 Cervical Spine Surgeries in NIS Database From 2001 to 2013

	All	ACF	PCF	PCD	ACF and PCF
Total cases	419,830	338,177	31,673	41,975	8005
Variables					
Patient and clinical characteristics					
Age (Mean, SD)	53.74 (12.36)	52.26 (11.75)	60.76 (12.59)	59.46 (13.31)	58.26 (11.95)
Patient gender					
Male	208,465 (49.7%)	160,823 (47.6%)	18,078 (57.1%)	25,252 (60.2%)	4312 (53.9%)
Female	210,825 (50.2%)	177,098 (52.4%)	13,557 (42.8%)	16,478 (39.3%)	3692 (46.1%)
Race					
White	269,962 (64.3%)	219,025 (64.8%)	20,341 (64.2%)	25,474 (60.7%)	5122 (64.0%)
Black	31,523 (7.5%)	23,785 (7.0%)	3648 (11.5%)	3279 (7.8%)	811 (10.1%)
Hispanic	17,066 (4.1%)	13,462 (4.0%)	1545 (4.9%)	1680 (4.0%)	379 (4.7%)
Other	13,581 (3.2%)	10,498 (2.5%)	1216 (0.3%)	1543 (0.4%)	324 (0.1%)
Median income					
1st quartile: <$39k	64,021 (15.2%)	51,110 (15.1%)	5890 (18.6%)	5627 (13.4%)	1394 (17.4%)
2nd quartile: $39k–$47,999	69,532 (16.6%)	55,986 (16.6%)	5758 (18.2%)	6224 (14.8%)	1564 (19.5%)
3rd quartile: $48k–$62,999	70,303 (16.7%)	55,952 (16.5%)	5993 (18.9%)	6770 (16.1%)	1588 (19.8%)
4th quartile: >$63k	64,223 (15.3%)	50,443 (14.9%)	5746 (18.1%)	6501 (15.5%)	1533 (19.2%)
Insurance					
Private including HMO	231,844 (55.2%)	196,854 (58.2%)	12,290 (38.8%)	19,026 (45.3%)	3674 (45.9%)
Medicare	110,705 (26.4%)	76,576 (22.6%)	14,335 (45.3%)	16,748 (39.9%)	3046 (38.1%)
Medicaid	23,752 (5.7%)	18,887 (5.6%)	2168 (6.8%)	2201 (5.2%)	496 (6.2%)
Other	52,577 (12.5%)	45,060 (10.7%)	2818 (0.7%)	3929 (0.9%)	770 (0.2%)
Mortality risk					
Minor	348,277 (83.0%)	290,333 (85.9%)	22,215 (70.1%)	30,532 (72.7%)	5197 (64.9%)
Moderate	30,607 (7.3%)	18,140 (5.4%)	5694 (18.0%)	5333 (12.7%)	1440 (18.0%)
Major/Extreme	11,229 (2.7%)	5251 (1.3%)	2617 (0.6%)	2179 (0.5%)	1182 (0.3%)
Severity of illness					
Minor	253,025 (60.3%)	228,342 (67.5%)	13,426 (42.4%)	8743 (20.8%)	2514 (31.4%)
Moderate	113,759 (27.1%)	73,977 (21.9%)	12,034 (38.0%)	24,698 (58.8%)	3050 (38.1%)
Major/Extreme	23,329 (5.6%)	11,405 (2.7%)	5066 (1.2%)	4603 (1.1%)	2255 (0.5%)
Transferred in					
No	207,520 (49.4%)	164,774 (48.7%)	18,855 (59.5%)	18,908 (45.0%)	4983 (62.2%)
Yes	3349 (0.8%)	1714 (0.5%)	831 (2.6%)	577 (1.4%)	227 (2.8%)
LOS, mean (SD)	2.5 (4.06)	1.96 (3.00)	5.31 (6.43)	3.85 (5.51)	7.41 (9.15)
Chronic conditions, mean (SD)	3.98 (2.56)	3.75 (2.41)	5.04 (2.94)	4.48 (2.88)	5.4 (2.94)
Admission type					
Nonelective	47,417 (11.3%)	33,603 (9.9%)	5914 (18.7%)	6172 (14.7%)	1728 (21.6%)
Elective	344,628 (82.1%)	281,565 (83.3%)	24,693 (78.0%)	32,268 (76.9%)	6102 (76.2%)
Hospital characteristics					
Bed size					
Small	52,327 (12.5%)	43,885 (13.0%)	3041 (9.6%)	4688 (11.2%)	713 (8.9%)
Medium	93,731 (22.3%)	77,018 (22.8%)	6252 (19.7%)	8809 (21.0%)	1652 (20.6%)
Large	271,962 (64.8%)	215,785 (63.8%)	22,244 (70.2%)	28,335 (67.5%)	5598 (69.9%)
Wage index, mean (SD)	1.01 (0.15)	1.01 (0.14)	1.03 (0.15)	1.04 (0.16)	1.04 (0.16)
Hospital type					
Urban non-teaching/Rural	197,574 (47.1%)	168,379 (49.8%)	9869 (31.2%)	16,132 (38.4%)	3194 (39.9%)
Urban teaching	220,446 (52.5%)	168,309 (49.8%)	21,668 (68.4%)	25,700 (61.2%)	4769 (59.6%)
Hospital region					
Northeast region	63,600 (15.1%)	49,000 (14.5%)	6566 (20.7%)	6779 (16.2%)	1255 (15.7%)
Midwest region	91,993 (21.9%)	73,109 (21.6%)	6806 (21.5%)	10,276 (24.5%)	1802 (22.5%)
South region	182,258 (43.4%)	152,508 (45.1%)	12,292 (38.8%)	14,615 (34.8%)	2843 (35.5%)
West region	81,979 (19.5%)	63,560 (18.8%)	6009 (19.0%)	10,305 (24.6%)	2105 (26.3%)

Number of cases and % of total are presented unless otherwise specified. Note that percentages do not always equal 100% due to missing data.
ACF indicates anterior cervical fusion; PCD, posterior cervical decompression; PCF, posterior cervical fusion; SD, standard deviation.

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TABLE 2. Mean Cost in 2013 Inflation-Adjusted U.S. Dollars (Standard Error in Parenthesis) for All Types of Cervical Spine Surgery Combined in NIS database From 2001 to 2013

Year	No. of Cases	U.S. Cost, Mean (SE)	Northeast Cost, Mean (SE)	Midwest Cost, Mean (SE)	South Cost, Mean (SE)	West Cost, Mean (SE)
2001	27,061	$11,799 ($274)	$12,055 ($786)	$11,349 ($558)	$11,350 ($442)	$12,900 ($541)
2002	28,624	$12,717 ($274)	$11,892 ($742)	$12,279 ($509)	$12,226 ($322)	$14,563 ($737)
2003	31,384	$13,452 ($368)	$11,751 ($858)	$12,395 ($488)	$13,178 ($546)	$16,302 ($1074)
2004	28,408	$15,090 ($372)	$15,580 ($1203)	$14,152 ($626)	$15,047 ($614)	$15,908 ($685)
2005	30,057	$15,045 ($379)	$14,498 ($839)	$14,762 ($794)	$14,158 ($500)	$17,739 ($964)
2006	30,867	$15,510 ($322)	$15,645 ($648)	$14,865 ($583)	$14,931 ($482)	$17,885 ($869)
2007	31,825	$16,925 ($368)	$15,987 ($792)	$16,205 ($811)	$16,270 ($552)	$19,894 ($739)
2008	34,107	$17,363 ($431)	$18,983 ($1680)	$16,237 ($699)	$16,290 ($588)	$20,519 ($941)
2009	34,170	$17,313 ($398)	$16,132 ($922)	$17,141 ($714)	$16,352 ($595)	$20,522 ($931)
2010	35,864	$18,971 ($524)	$17,227 ($1393)	$17,746 ($1022)	$18,620 ($720)	$22,085 ($1358)
2011	38,777	$19,060 ($471)	$18,374 ($1265)	$16,910 ($642)	$17,960 ($588)	$24,113 ($1301)
2012	34,104	$18,989 ($266)	$17,298 ($559)	$18,334 ($429)	$17,842 ($392)	$23,553 ($719)
2013	34,582	$19,379 ($266)	$17,786 ($507)	$18,239 ($453)	$18,415 ($415)	$24,066 ($693)

SE indicates standard error.

cases were performed at large hospitals (64.8%), although nearly half of the cases were performed at rural or urban non-teaching hospitals (47.1%). The greatest number of cervical spine cases were performed in the southern U.S. (n = 182,258; 43.4% of all cases performed in U.S; Table 1).

Although the number of actual procedures increased slightly from 2001 (n = 27,061) to 2013 (n = 34,582; Table 2), the national rates of all types of cervical spine surgery (per 100,000 adult population) decreased slightly from 2001 to 2013, from 75.34 to 72.20 per 100,000 adults (Figure 1). The rates of ACF and PCD decreased over this period of time (ACF: from 62.39 to 56.21; PCD: from 9.66 to 6.31), while the rates of PCF and APCF increased (PCF: from 2.86 to 7.81; ACPF: from 0.43 to 1.86 per 100,000 adults; Figure 1). Across all years from 2001 to 2013, the highest rate of cervical spine surgery was performed in the southern U.S. (South 2001: 90.70 *vs.* 63.89, 65.44, and 70.53 in Northeast, West, and Midwest, respectively; South 2013: 81.22 *vs.* 63.07, 65.97, and 71.70 in West, Northeast, and Midwest, respectively; Figure 2). From 2001 to 2013, the rate of cervical spine surgery decreased slightly in the South (90.70 in 2001 to 81.22 in 2013 per 100,000 adults),

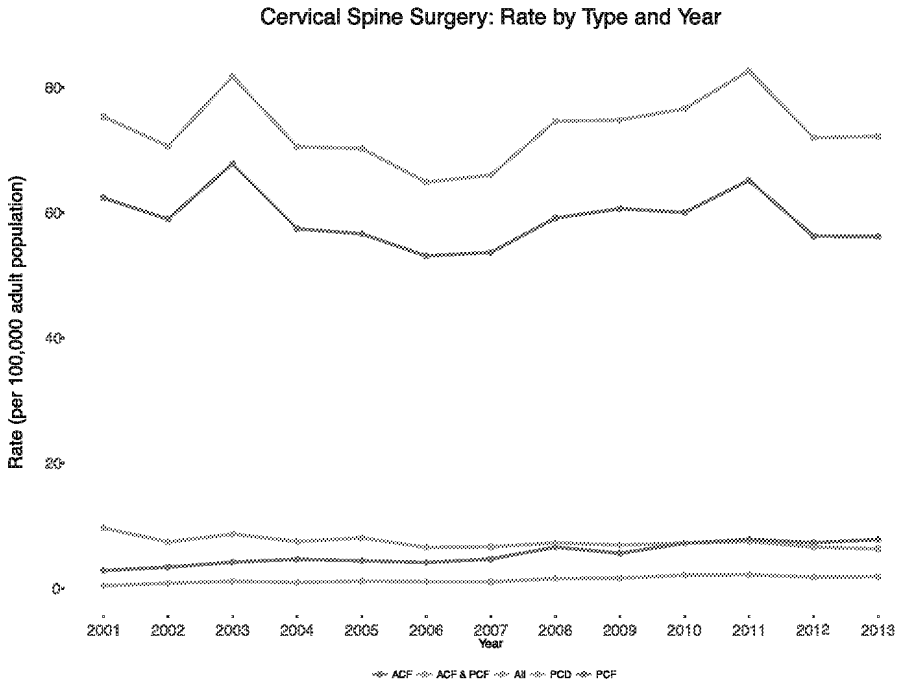

Figure 1. Temporal trends in national rates of different types of cervical spinal surgery (all, ACF, PCF, PCD, ACF, and PCF) in NIS database from 2001 to 2013. ACF indicates anterior cervical fusion; PCD, posterior cervical decompression; PCF, posterior cervical fusion.

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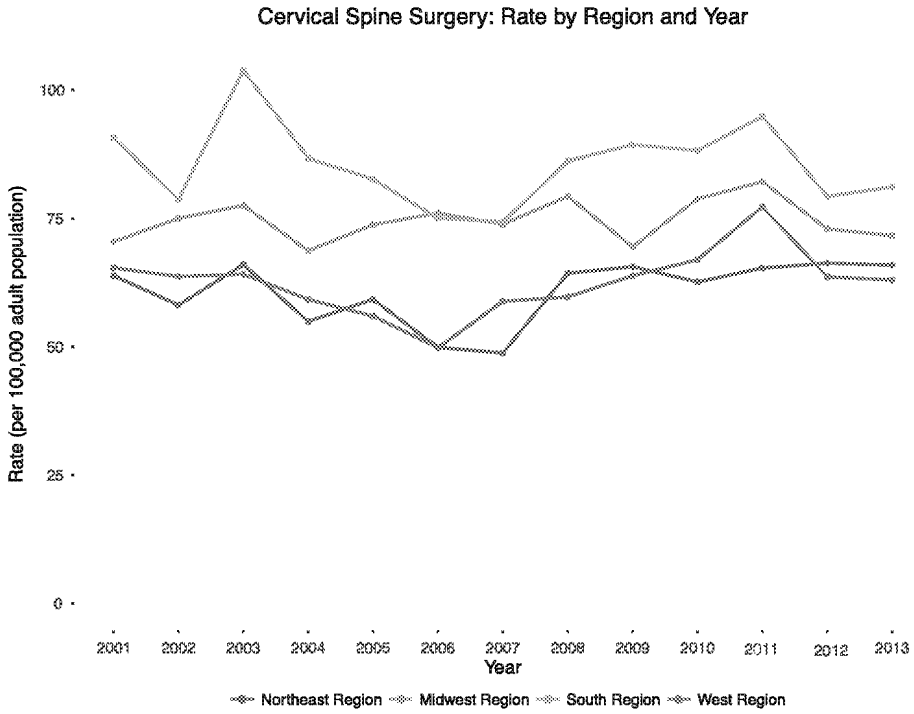

Figure 2. Temporal and geographic trends in all types of cervical spinal surgery in NIS database from 2001 to 2013.

while it remained relatively constant in the remaining regions of the U.S. (Northeast: 63.89 in 2001 *vs.* 65.97 in 2013; Midwest: 70.53 in 2001 *vs.* 71.70 in 2013; West: 65.44 in 2001 *vs.* 63.07; Figure 2).

Between 2001 and 2013, the national inflation-adjusted mean cost of cervical spine surgery increased by 64.2%, from $11,799 to $19,379. The western United States was the highest costing region for cervical spine surgery from 2001 through 2013 (Table 2; Figure 3). The Northeastern U.S. was the second most expensive region in 2001 ($12,055 *vs.* $11,799 national mean), but became the least expensive region by 2013 ($17,786 *vs.* $19,379 national mean; Table 2; Figure 3).

Univariate analyses showed the following patient factors were associated with higher surgical costs: older age, male gender, Black/Hispanic/Other race (*vs.* white), patient residing in a central county metro area with >1 million population, higher median income of patient zipcode, Medicare/Medicaid/Other insurance (*vs.* private), higher risk of mortality, higher severity of illness, patients transferred from another hospital, longer LOS, nonelective admission, and greater number of medical comorbidities (all $P < 0.05$; Table 3). For hospital factors, the wage index was positively correlated with surgical cost, urban teaching hospitals were more costly than urban non-teaching/ rural hospitals, and the western region was associated with higher costs than the Northeast (all $P < 0.01$; Table 3).

In multivariate analyses, older age was associated with a higher cost: there was a 3% cost increase per 10 additional years of age ($P < 0.001$; Table 4). Males had 2% higher costs overall than females ($P < 0.001$; Table 4). Black patients and those of "other" races were more costly than white patients (Table 4). Increasing LOS and higher mortality risk and severity of illness were also associated with higher costs for cervical spine surgery. In particular, patients with major/extreme severity of illness had 25% higher cost than those with minor severity of illness ($P < 0.001$; Table 4). In terms of hospital characteristics, only wage index and geographic region were associated with cost after controlling for other factors in our multivariate analyses. More specifically, cervical surgery costs were 27% higher in the western than in the northeastern U.S. ($P < 0.001$; Table 4).

DISCUSSION

Our study shows that the rate of cervical spine surgery for degenerative disease decreased slightly from 2001 to 2013. This is in contrast to the rate of lumbar spine surgery for degenerative disease[13] and fusions for spinal deformity, both of which increased significantly over this period of time. More specifically, the rate of fusions for spinal deformity increased 250% from 2001 to 2013. One possible explanation for the slight decrease in rates of cervical spine surgery is that we have now reached a stable national level of these surgeries after preceding decades of extreme growth, as documented in studies of the NIS database 1990 to 2000[5] and the Medicare database from 1992 to 2005.[4] Another possibility is that more cervical disk arthroplasties are being performed in the past decade, rather than fusions. Finally, surgeons may be coding for "kyphosis" and spinal deformity more recently, which are not captured in our cases of cervical spine surgery for degenerative disease only.

In addition, the inflation-adjusted mean cost per cervical spinal surgery increased 64% from 2001 to 2013, exceeding the 31.6% rate of inflation.[12] This steep rise in costs is similar to the increase in costs for other types of spine surgery, including lumbar laminectomy and fusion for degenerative conditions[13] and fusion for adult spinal deformity.[14]

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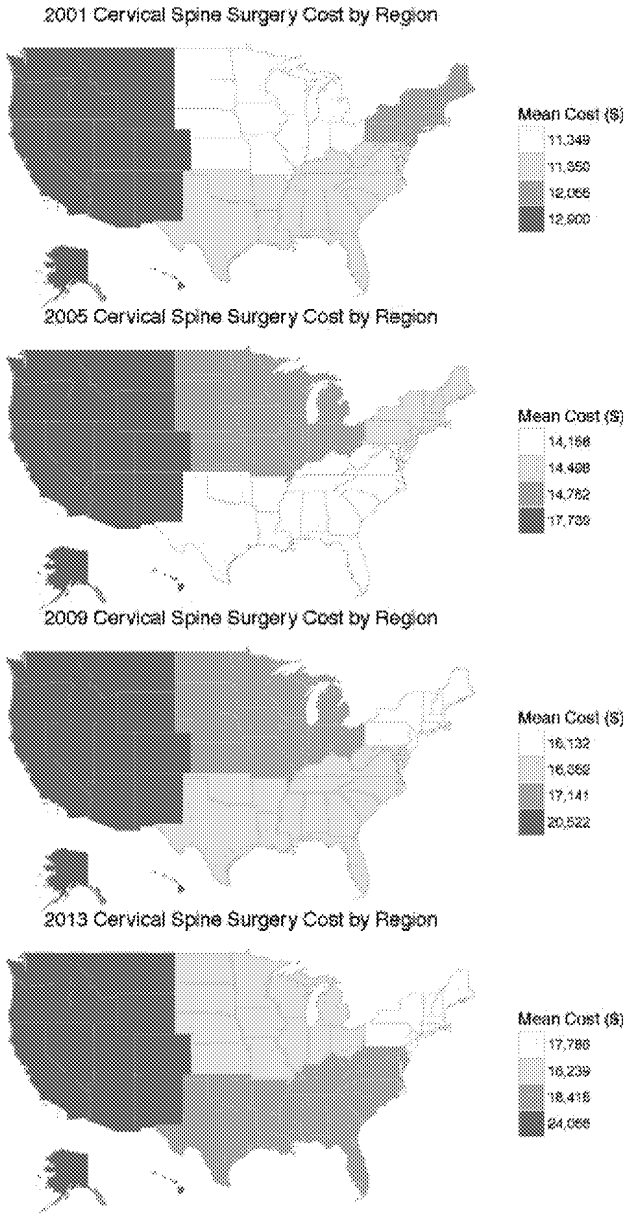

Figure 3. Geographic variation in mean cost for cervical spine surgery (n = 419,830) in NIS database from 2001 to 2013.

Another important finding is that several patient factors (age, gender, race, insurance, risk of mortality/severity of illness) and hospital factors (wage index, geographic region) were associated with higher costs for cervical spine surgery. Even after controlling for patient and hospital factors, there was significant geographic variation in the cost for cervical spine surgery, with the western region being the most expensive region in the United States. This finding of significant regional cost variation is consistent with results from other studies in spine surgery[10,13–17] and major joint arthroplasty.[11] Possible explanations for the higher costs in the western U.S. include failure of wage index to adjust adequately for high labor costs and real estate in expensive western cities, and regional policies such as minimum nurse-patient ratios in California.[18]

TABLE 3. Univariate Analysis of Predictors of Total Cost for Cervical Spine Surgery

Variables	Mean Cost, $ (SE)	*P*
Patient and clinical factors		
Age, yrs, quartiles		
Q1: <45	13,817 (137)	
Q2: 46–52	15,360 (151)	<0.001‡
Q3: 52–62	17,318 (175)	<0.001‡
Q4: >62	19,863 (211)	<0.001‡
Gender		
Male	17,150 (176)	
Female	15,918 (155)	<0.001‡
Race		
White	16,411 (173)	
Black	20,044 (298)	<0.001‡
Hispanic	19,871 (441)	<0.001‡
Other	19,864 (493)	<0.001‡
Patient county of residence		
Central county metro area >1 million pop	22,324 (494)	
Fringe county of metro area >1 million	19,290 (354)	<0.001‡
County in metro area 250–999k	18,136 (415)	<0.001‡
County in metro area 50–250k	18,757 (427)	<0.001‡
Micropolitan county (<50k)	17,807 (393)	<0.001‡
Not metropolitan or micropolitan	17,473 (526)	<0.001‡
Median income in patient zipcode		
Q1: <$39k	17,944 (242)	
Q2: $39k–47,999	17,607 (186)	0.039*
Q3: $48k–62,999	17,842 (210)	0.641
Q4: >$63k	18,662 (272)	0.022*
Insurance		
Private	15,072 (149)	
Medicare	19,311 (204)	<0.001‡
Medicaid	19,070 (271)	<0.001‡
Other	15,864 (219)	<0.001‡
Mortality risk		
Minor	15,138 (140)	
Moderate	23,948 (270)	<0.001‡
Major/Extreme	50,854 (720)	<0.001‡
Severity of illness	14,280 (127)	
Minor	17,602 (179)	<0.001‡
Moderate	41,216 (514)	<0.001‡
Major/Extreme		
Patient transferred in		
No	18,244 (194)	
Yes	36,967 (1040)	<0.001‡
Length of stay (days, quartiles)		
Q1 and Q2: 1	12,458 (109)	<0.001‡
Q3: 2	15,177 (143)	<0.001‡
Q4: >2	26,914 (279)	
Elective admission		<0.001‡
No	25,299 (143)	

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TABLE 3. (Continued)

Variables	Mean Cost, $ (SE)	P
Yes	15,702 (154)	<0.001‡
Chronic conditions (number, quartiles)		<0.001‡
Q1: <=2	15,431 (175)	<0.001‡
Q2: 2–3	24,197 (326)	<0.001‡
Q3: 304	173,902 (183)	<0.001‡
Q4: >5	19,063 (217)	<0.001‡
Hospital factors		
Bedsize		
Small	16,080 (419)	
Medium	16,363 (331)	0.596
Large	16,655 (209)	0.224
Wage index (quartiles)		
Q1: <0.9093	14,772 (222)	
Q2: 0.9093–0.978	16,032 (291)	<0.001‡
Q3: 0.978–1.0945	16,869 (338)	<0.001‡
Q4: >1.0945	18,517 (380)	<0.001‡
Hospital type		
Urban non-teaching/Rural	16,014 (206)	
Urban teaching	16,979 (251)	0.003†
Hospital region		
Northeast	15,752 (456)	
Midwest	15,497 (292)	0.636
South	15,940 (237)	0.716
West	19,535 (409)	<0.001‡

*Statistical significance with $P < 0.05$.
†Statistically significant with $P < 0.01$.
‡Statistically significant with $P < 0.001$.
Q indicates quartile; SE, standard error.

TABLE 4. Multivariate Analysis of Predictors of Total Cost for Cervical Spine Surgery

Patient/Clinical Factors	Estimate	P	Significance
Age (10-yr increments)	1.03	<0.001	‡
Gender (Female vs. male)	0.98	<0.001	‡
Race (vs. White)			
Black	1.05	<0.001	‡
Hispanic	1	0.75	
Other	1.04	0.008	†
Insurance (vs. Private)			
Medicare	0.98	<0.001	‡
Medicaid	1.01	0.14	
Other	1	0.933	
Mortality risk (vs. Minor)			
Moderate	1.05	<0.001	‡
Major/Extreme	1.02	0.17	
Severity of illness (vs. Minor)			
Moderate	1.06	<0.001	‡
Major/Extreme	1.25	<0.001	‡
Length of stay (1-day increments)	1.08	<0.001	‡
Elective admission (vs. nonelective)	1.01	0.504	
Hospital Factors			
Bedsize (vs. Small)			
Medium	0.99	0.714	
Large	0.95	0.069	
Wage index (0.1 increments)	1.06	<0.001	‡
Hospital type (vs. Urban non-Teaching/Rural):			
Urban Teaching	0.98	0.377	
Hospital region (vs. Northeast)			
Midwest region	1.22	<0.001	‡
South region	1.2	<0.001	‡
West region	1.27	<0.001	‡

*Statistical significance with $P < 0.05$.
†$P < 0.01$.
‡$P < 0.001$.

Limitations of our study include the reliance on coding data in the NIS database, as well as the derivation of costs from charges. The NIS dataset grew significantly in terms of its geographic representation from 2001 to 2013, which may explain part of the differences in rates of surgical utilization from year to year. In addition, we are unable to determine the number of levels of spine surgery in the NIS dataset, which is obviously a confounder, as a five-level cervical fusion is much more costly than a one-level cervical fusion. However, we do not have any reason to believe that surgeons in the western U.S. operate on more levels than those in other parts of the country, and in fact, the rates of cervical spine surgery overall are lower in the West than in other parts of the U.S.

In conclusion, several important patient and hospital factors drive cost in cervical spine surgery. Any studies or publically available databases that attempt to compare costs between institutions must adequately account for these differences.

Key Points

- The national rates of all cervical spine surgery decreased slightly from 2001 to 2013.
- The mean inflation-adjusted cost for cervical spine surgery increased by 64% from 2001 to 2013.
- Several patient (age, gender, race, insurance, risk of mortality/severity of illness) and hospital factors (wage index, geographic region) were associated with higher costs for cervical spine surgery.
- Even after controlling for patient and hospital factors, there was a significant geographic variation in the cost for cervical spine surgery, with the western region being the most expensive region in the United States.

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Original Article Clinics in Orthopedic Surgery 2011;3:39-47 • doi:10.4055/cios.2011.3.1.39

Fusion Rates of Instrumented Lumbar Spinal Arthrodesis according to Surgical Approach: A Systematic Review of Randomized Trials

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Background: Lumbar spine fusion rates can vary according to the surgical technique. Although many studies on spinal fusion have been conducted and reported, the heterogeneity of the study designs and data handling make it difficult to identify which approach yields the highest fusion rate. This paper reviews studies that compared the lumbosacral fusion rates achieved with different surgical techniques.

Methods: Relevant randomized trials comparing the fusion rates of different surgical approaches for instrumented lumbosacral spinal fusion surgery were identified through highly sensitive and targeted keyword search strategies. A methodological quality assessment was performed according to the checklist suggested by the Cochrane Collaboration Back Review Group. Qualitative analysis was performed.

Results: A literature search identified six randomized controlled trials (RCTs) comparing the fusion rates of different surgical approaches. One trial compared anterior lumbar interbody fusion (ALIF) plus adjunctive posterior transpedicular instrumentation with circumferential fusion and posterolateral fusion (PLF) with posterior lumbar interbody fusion (PLIF). Three studies compared PLF with circumferential fusion. One study compared three fusion approaches: PLF, PLIF and circumferential fusion.

Conclusions: One low quality RCT reported no difference in fusion rate between ALIF with posterior transpedicular instrumentation and circumferential fusion, and PLIF and circumferential fusion. There is moderate evidence suggesting no difference in fusion rate between PLF and PLIF. The evidence on the fusion rate of circumferential fusion compared to PLF from qualitative analysis was conflicting. However, no general conclusion could be made due to the scarcity of data, heterogeneity of the trials included, and some methodological defects of the six studies reviewed.

Keywords: *Systematic review, Spinal fusion, Surgical approach*

Surgical fusion is the mainstay in the treatment of degenerative disorders of the lumbar spine. Many spinal fusion techniques have been developed since the initial description of spinal fusion in the early 20th century. Traditional posterolateral intertransverse fusion (PLF) still remains a useful procedure with acceptable fusion rates for most degenerative conditions. Interbody fusion techniques using either anterior (anterior lumbar interbody fusion, ALIF) or posterior (posterior lumbar interbody fusion, PLIF) approaches have been developed to restore the structural integrity of degenerative or unstable discs. However, there is no solid evidence showing that the functional outcomes are better after anterior column support than other fusion models.[1,2] Harms introduced transforaminal interbody fusion (TLIF) to overcome the issue of dural manipulation and subsequent epidural fibrosis.[3] For solid fusion, PLF can be combined with interbody fusion to circumferentially stabilize the relevant segment, even though it is unclear

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whether this improves the fusion rates.[4-8]

The fusion rates in lumbar spine surgery can vary according to the technique. Although numerous studies on spinal fusion have been conducted, their outcomes are so inconsistent that it is difficult to determine which approach provides the highest fusion rate. Therefore, in this study, an attempt was made to identify all relevant randomized controlled trials (RCTs) comparing fusion techniques. In addition, a systematic review was performed to summarize and describe the contemporary best evidence.

METHODS

Literature Search

A computer assisted search of Medline (from 1966 to September 2008) was conducted to retrieve all the relevant randomized controlled trials. The highly sensitive search strategies suggested by others[9,10] were used, and the specific search terms included the following: spine fusion, spinal fusion, posterolateral lumbar fusion, posterior lumbar interbody fusion, transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, circumferential fusion, spinal arthrodesis and spondylodesis. The relevant RCTs from the Cochrane Central Register of Controlled Trials (3rd quarter 2008) with similar terms were also identified. The search was limited to English language publications and complete articles from peer-reviewed journals. The references were screened from articles selected based on the abstract.

Selection

The titles and abstracts of the identified studies were reviewed, and possible studies were retrieved in the full text version. Only RCTs reporting the results of instrumented lumbar spinal fusion for degenerative conditions were included. Studies involving patients with spinal fractures, tumors, infections or scoliosis were excluded. Studies that compared lumbar fusion with artificial disc replacement, dynamic stabilization, electrical stimulation or any conservative treatment were excluded. Because the purpose of the study was to examine the fusion rates according to the surgical approach, only those studies that compared fusion rates of two or more surgical approaches were included. Accordingly, studies comparing different instrumentation with the same approach were also excluded. The trials must have reported the fusion rate as an outcome measure.

Methodological Quality Assessment

The studies that met all the above criteria were reviewed closely in terms of the methodological quality using the checklist suggested by the Cochrane Collaboration Back Review Group (BRG).[10] The criteria were assessed by two reviewers and scored as 'yes,' 'no,' or 'don't know.'

Data Extraction

The data was extracted using a data extraction form included in the Cochrane Handbook for Systematic Reviews for Interventions (Chapter 7, version 5.0.0). One reviewer extracted the data and a second reviewer confirmed them. The checklist contains the study characteristics of methods, participants, interventions, outcomes and results.

Data Analysis

For the outcome of fusion, the relative risk (RR) and 95% confidence interval (CI) were calculated. A chi-square analysis was performed for each study to determine the statistical significance. The results were considered significant at $p < 0.05$ and two-tailed values were used. Meta-analysis was not possible due to the heterogeneity of the outcome definitions and scarcity of valid data allowing for only qualitative analysis.[10]

RESULTS

Literature Search

The highly sensitive search for controlled trials and spinal fusion retrieved 5,064 references in Medline. The literature regarding 'cervical' or 'scoliosis' were excluded using the 'NOT' prefix. After screening the titles of the remaining 2,700 references, the abstracts of 312 potentially relevant articles were reviewed. Finally, six articles that satisfied all the inclusion/exclusion criteria were obtained. A search of the Cochrane Central Register of Controlled Trials identified 466 references in which all six studies were included. There was no additional study found in the Cochrane search and reference screening of the selected articles.

Study Characteristics

Table 1 summarizes the characteristics of the six studies included in this study. Three studies[5-7] included the three intervention groups, and two had non-relevant groups, such as noninstrumented fusion (Fritzell et al.[5]) or foraminotomy (Hallett et al.[6]). A total of 526 patients in the 6 studies were followed to the last follow-up period. There were 220 PLF patients, 215 circumferential fusion patients, 67 PLIF patients and 22 ALIF patients. All PLIF and ALIF patients underwent transpedicular instrumentation. Five studies compared circumferential fusion with other fusion approaches but the approaches combined with PLF were heterogeneous. The timing of the outcome assessment in-

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Table 1. Summary of the Trials Included

	Schofferman et al.[8]	Fritzell et al.[5]	Christensen et al.[4]	Kim et al.[7]	Inamdar et al.[11]	Hallett et al.[6]
Year published	2001	2002	2002	2006	2006	2007
			Participants			
Total no.	53	222	148	184	22	48
Fusion level	1 or 2 or 3 levels	1 or 2 levels (L4-5, L5-S1)	1 or 2 levels	1 or 2 levels	1 level (L4-5 or L5-S1)	1 level (L3-4 or L4-5 or L5-S1)
Inclusion criteria	Structural problem amenable to fusion, failed conservative care, no psychological contraindications	Severe and therapy resistant CLBP, pain duration at least 2 years, back pain is severer than leg pain, no sign of nerve root compression	Severe CLBP and leg pain	Disabling back pain and/or leg pain with or without neurologic symptoms, neural canal stenosis on MRI	Neurogenic claudication, neurological deficits, severe persistent backache, high-grade slip with instability	Single level degenerative disc disease, foraminal stenosis with leg pain
Diagnosis	FBS, painful degenerated disc, SS, SL	NS	Isthmic SL grade 1-2, primary degeneration, secondary or accelerating degeneration after decompressive surgery	SS, isthmic SL, degenerative SL	Isthmic and degenerative SL	Same as above
Exclusion criteria	NS	Previous spine surgery except for successful removal of a herniated disc, SL, SS	Previous surgery, age < 20 or > 65, metabolic bone disease, comorbidity, psychosocial instability	Fracture, infection, tumor, revision, secondary gains	NS	Degenerative SL > grade 2, vertebral translocation > 1 cm, disc space narrowing > 50%, malignancy
Country	United States	Sweden	Denmark	Korea	India	Scotland
			Intervention			
Intervention groups	1. 360° fusion: ALIF + PLF with instrumentation 2. 270° fusion: ALIF with instrumentation	(1. PLF without instrumentation) 2. PLF with instrumentation 3. PLF + ALIF or PLIF	1. PLF 2. ALIF + PLF	1. PLF 2. PLIF 3. PLF + PLIF	1. PLIF 2. PLF	(1. Foraminotomy only) 2. PLF 3. PLF + TLIF
Instrumentation	TSRH transpedicular	VSP and internal fixation device	CDI or transarticular screws Brantigan cages for ALIF	TSRH pedicle screws Harms mesh cages for PLIF	Moss Miami pedicle screws	Moss Miami pedicle screws Titanium interbody cages for TLIF
Bone graft	ALIF : FRA with allograft chips PLF: autogenous ICBG	Autogenous ICBG (tricortical bone block for interbody fusion)	Autogenous ICBG	PLF: autogenous ICBG + local bone PLIF: local bone with cage	PLIF: autogenous tricortical ICBG PLF: spinous process with BG substitute	Autogenous ICBG

cluding the fusion status ranged from one and three years after surgery.

Only Hallett et al.'s study[6] included single level fusion, but various segments were fused (L3-4, L4-5, L5-S1). Two or three level fusions were mixed in the other studies. The diagnostic inclusion criteria in these studies were also heterogeneous. However, study groups in each study were generally similar in terms of the prognostic indicators. An autogenous iliac bone graft was harvested in most studies except for the ALIF group in Schofferman et al.'s study[8] in which a femoral ring allograft and decalcified allograft chips were used. For the other interbody fusions, two studies[5,11] employed autogenous tricortical bone blocks and three studies[4,6,7] used various cages (Table 1).

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Table 1. Continued

	Schofferman et al.[6]	Fritzell et al.[5]	Christensen et al.[4]	Kim et al.[7]	Inamdar et al.[11]	Hallett et al.[8]
Year published	2001	2002	2002	2006	2006	2007
			Outcomes			
Time point	1 yr	2 yr	1 yr	6 mo, 1 yr, 2 yr, 3 yr	1 yr	2 yr
Definition	Refer to Table 2.					
			Results			
No. of participants allocated	1. 29 2. 24	2. 74 3. 75	1. 73 2. 75	NS	1. 11 2. 11	2. 16 3. 14
Age (range)	1. 43 (24-57) 2. 40 (25-54)	2. 43 (25-65) 3. 42 (28-59)	1. 45.5 (23-65) 2. 45.4 (20-63)	1. 58.6 (42-74) 2. 55.2 (38-79) 3. 53.4 (39-75)	1. 41.4 2. 44.7	2. 54 3. 59
Gender	1. M 14, F 12 2. M 13, F 9	2. M 60.8% 3. M 40.0%	1. M 27, F 46 2. M 31, F 42	1. M 15, F 47 2. M 17, F 40 3. M 13, F 35	NS	2. M 6, F 10 3. M 9, F 5
Missing participants	1. 3 (X-ray available for 22) 2. 2 (X-ray available for 18)	NS	1. 2 2. 3	17	1. 1 2. 1	2. 1 at 2 yr, 5 at 5 yr 3. 1 at 2 yr, 5 at 5 yr
Fusion rate	1. 77% (17/22) 2. 89% (16/18)	2. 87% (54/62) 3. 91% (58/64)	1. 80% (57/71) 2. PLF: 92% (67/72), ALIF: 82% (60/72)	1. 92% (57/62) 2. 95% (54/57) 3. 93% (46/48)	1. 100% 2. 100%	2 and 3. PLF 95% (26/28) 3. TLIF 46% (6/13)
RR	0.869	0.961 (2 vs. 3)	0.863 (PLF1 vs. PLF2) 0.963 (PLF1 vs. ALIF)	Not possible	1	Not possible
Confidence interval	0.657-1.150	0.849-1.088 (2 vs. 3)	0.757-0.984 (PLF1 vs. PLF2) 0.825-1.125 (PLF1 vs. ALIF)	Not possible	1	Not possible
p-value	0.336	0.529 (2 vs. 3)	0.024 (PLF1 vs. PLF2) 0.636 (PLF1 vs. ALIF)	0.667	1	Not possible
Remarks	Very low PLF rate			Fusion rates at last follow-up		

The numbers (1, 2, 3) indicate the corresponding groups in each study. Group 1 data in the Fritzell[5] and Hallett[8] studies were not included in the present analysis. CLBP: chronic low back pain, MRI: magnetic resonance imaging, FBS: failed back surgery, SS: spinal stenosis, SL: spondylolisthesis, NS: not specified, ALIF: anterior lumbar interbody fusion, PLF: posterolateral fusion, PLIF: posterior lumbar interbody fusion, TLIF: transforaminal interbody fusion, TSRH: Texas Scottish Rite Hospital, VSP: variable screw placement, CDI: Cotrel-Dubousset instrumentation, FRA: femoral ring allograft, ICBG: iliac crest bone graft, RR: relative risk.

All studies evaluated spinal fusion from simple radiographs with or without flexion-extension views. However, the definitions of fusion were quite heterogeneous. For PLF, three authors (Christensen et al.,[4] Kim et al.,[7] Hallett et al.[6]) defined fusion as a bony bridge between transverse processes on at least one side, whereas Fritzell[5] defined fusion as bridging trabeculae on both sides. The other two studies[8,11] did not specify the bilaterality of fusion. The definitions for interbody fusion were relatively similar. For circumferential fusion, either the criteria of interbody fusion or PLF was used in some studies, whereas the other studies reported the fusion rates of interbody fusion and PLF separately (Table 2).

Methodological Quality

According to the criteria list of BRG,[10] the trials were scored between 3 and 7 out of 11 possible points (Table 3). Only two studies had more than six points, and were referred to as 'high quality' studies.[12] Three studies (Fritzell et al.,[5] Christensen et al.,[4] Hallett et al.[6]) described an acceptable randomization process including sequence generation and allocation concealment.[13,14] In Schofferman et

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Table 2. Definitions of Fusion

	PLF	Interbody fusion	Circumferential fusion
Schofferman et al.[8]	Mature bridging trabeculae with remodeling, no radiolucent lines, no motion on flexion/extension radiographs	No radiolucent lines, no motion, remodeling of FRA with trabeculation and density equal to the adjacent vertebra	Separately (ALIF or PLF)
Fritzell et al.[5]	Trabeculae on both sides with evidence of increasing density with cortication	Trabeculae on both sides	Interbody fusion was assumed to be sufficient
Christensen et al.[4]	Continuous intertransverse bony bridge on at least 1 side	Continuous trabecular bony structure	Separately (ALIF or PLF)
Kim et al.[7]	Lenke classification: results above B level were considered fusion	Bony bridge, < 5 degrees movement on flexion/extension views, absence of radiolucency around the cage and cage migration	Either the criteria of group 1 or 2
Inamdar et al.[11]	Grade 0: no visible gap Grade 1: amorphous noncontiguous bone Grade 2: amorphous contiguous bone Grade 3: trabecular bone	Same as PLF grade 0 and 1: pseudoarthrosis Grade 2 and 3: good union	
Hallett et al.[6]	Continuous bony bridge on at least 1 side	Solid bar of bone within or anterior to cages	Separately (TLIF or PLF)

PLF: posterior lumbar fusion, FRA: femoral ring allograft, ALIF: anterior lumbar interbody fusion, TLIF: transforaminal interbody fusion.

Table 3. Assessment of the Methodological Quality

Criteria[18]	Schofferman et al.[8]	Fritzell et al.[5]	Christensen et al.[4]	Kim et al.[7]	Inamdar et al.[11]	Hallett et al.[6]
Was the method of randomization adequate?	No	Yes	Yes	Don't know	Don't know	Yes
Was the treatment allocation concealed?	No	Yes	Yes	Don't know	Don't know	Yes
Were the groups similar at baseline regarding the most important prognostic indicators?	Yes	No	Yes	Yes	Don't know	Yes
Was the patient blinded to the intervention?	Don't know	No	Don't know	Yes	Don't know	Don't know
Was the care provider blinded to the intervention?	No	No	No	No	No	No
Was the outcome assessor blinded to the intervention?	Yes	Yes	Don't know	Don't know	Don't know	No
Were cointerventions avoided or similar?	No	Yes	No	No	Yes	Yes
Was the compliance acceptable in all groups?	Yes	Yes	Yes	Yes	Yes	Yes
Was the drop-out rate described and acceptable?	No	Yes	No	Yes	Yes	Yes
Was the timing of the outcome assessment in all groups similar?	Yes	Yes	Yes	No	Don't know	Yes
Did the analysis include an intention-to-treat analysis?	No	No	No	No	No	Unclear
Score	4	7	5	4	3	7

al.'s study,[8] the patients were randomized into either the fusion group according to their clinic patient number. In the other two studies,[7,11] the authors did not report the method of randomization explicitly. Only one trial (Hallett et al.[6] reported an analysis explicitly described as an intention to treat.[13,15]

Fusion Rates and Qualitative Analysis

Schofferman et al.[8] compared 360° and 270° fusion methods. They designated an ALIF plus transpedicular instrumentation with PLF as '360° fusion,' and an ALIF plus transpedicular instrumentation without PLF as '270° fusion.' The fusion rates for ALIF and PLF were reported separately. ALIF in the 360° group appeared solid in 77%

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of patients, whereas ALIF in the 270° group was solid in 89%; this difference was not significant ($p = 0.336$) with a RR of 0.869 (95% CI, 0.657 to 1.150). In contrast, the fusion rate of PLF was quite low; 14% on both sides and 18% on one side in the 360° group. They concluded there were no significant clinical differences between the 360° and 270° fusion groups. However, the 270° fusions were associated with shorter operating times, less blood loss, reduced cost, and less utilization of health care resources.

In an RCT from the Swedish Lumbar Spine Study Group, Fritzell et al.[5] compared 3 surgical techniques: PLF without instrumentation, PLF with instrumentation and PLF with instrumentation and ALIF or PLIF (circumferential fusion). In the 360° group, interbody fusion that healed convincingly was assumed to be sufficient to be classified as solid fusion. The fusion rates for the PLF (with instrumentation) and 360° groups were 87% and 91%, respectively. There was no significant difference between the two approaches ($p = 0.529$; RR, 0.961; 95% CI, 0.849 to 1.088).

In the study reported by Christensen et al.,[4] circumferential fusion with a Brantigan cage (ALIF) was compared with PLF. Cotrel-Dubousset instrumentation (CDI) was used exclusively in the PLF group but either CDI or transarticular titanium screws were used in the circumferential group depending on whether decompression had been performed. They reported fusion rates of PLF and ALIF separately. In the PLF alone group, the fusion rate was 80%. In the circumferential group, the fusion rates of PLF and ALIF were 92% and 82%, respectively. The fusion rate of PLF in the circumferential group was significantly higher than that of the PLF group ($p = 0.024$; RR, 0.862; 95% CI, 0.757 to 0.984). Compared to the fusion rate of ALIF, the fusion rate of PLF group was similar to that of the circumferential group ($p = 0.636$; RR, 0.963; 95% CI, 0.825 to 1.125).

Kim et al.[7] compared the clinical outcomes of three fusion methods using the posterior approach: PLF, PLIF and circumferential fusion (PLF and PLIF). In the circumferential group, cases that satisfied either the criteria of PLF or PLIF were considered to be fusion. All three groups showed high union rates at the last follow-up; 92% for the PLF group, 95% for the PLIF group, and 93% for the circumferential group. There was no significant difference between union rates ($p = 0.667$).

Inamdar et al.[11] compared the PLF and PLIF in the treatment of spondylolisthesis. Only 11 patients were allocated to each group, and there was no incidence of pseudoarthrosis in either of the PLF and PLIF patients. They graded bony union from grade 0 to grade 3. In the PLIF group, 20% and 80% of patients showed evidence of grade 3 and 2 union, respectively. In the PLF group, 60% and 40% of patients showed evidence of grade 3 and 2 union, respectively.

Table 4. Levels of Evidence[10]

Strong	Consistent findings among multiple high quality RCTs
Moderate	Consistent findings among multiple low quality RCTs and/or CCTs and/or one high quality RCT
Limited	One low quality RCT and/or CCT
Conflicting	Inconsistent findings among multiple trials (RCTs and/or CCTs)
No evidence	No RCTs or CCTs

RCT: randomized controlled trial, CCT: controlled clinical trial.

A trial of Hallett et al.[6] included three groups: foraminotomy, foraminotomy with PLF, and foraminotomy with PLF and TLIF. Two circular titanium interbody cages were used in the TLIF fusion group. The fusion rate of PLF was much higher than TLIF because 95% of the patients undergoing PLF developed solid fusion, and solid interbody fusion was only apparent in 6 of the 13 patients assessed. However, statistical analysis was impossible because they did not report the results of PLF in the PLF and circumferential groups separately.

The above articles describe four different surgical approaches with varying fusion success rates. Qualitative analyses was performed using various levels of evidence (Table 4) suggested by the BRG[10] as follows:

1. There is limited evidence (1 trial; 40 patients) to indicate no difference in fusion rates between ALIF plus posterior transpedicular instrumentation and circumferential fusion (PLF and ALIF): Schofferman et al.[8]
2. There is limited evidence (1 trial; 110 patients) indicating that there is no difference in the fusion rates between PLIF and circumferential fusion (PLF and PLIF): Kim et al.[7]
3. There is moderate evidence (2 trials; 139 patients) suggesting no difference in fusion rates between PLF and PLIF: Kim et al.[7] and Inamdar et al.[11]
4. There is conflicting evidence (4 trials; 407 patients) regarding the fusion rate of circumferential fusion compared to PLF: Fritzell et al.,[5] Christensen et al.,[4] Kim et al.,[7] and Hallett et al.[6]

DISCUSSION

A range of surgical approaches can be used to achieve

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lumbar spinal fusion. Numerous investigators have reported the biomechanical and biological rationale, advantages and disadvantages, fusion rates and clinical results of each approach. However, the outcomes of the studies are so inconsistent that there is no evidence of the superiority of one approach over another one in terms of the fusion rate. This may be due to the diversity of the patient populations, diagnostic criteria of fusion, bone graft source or postoperative bracing. Therefore, randomized trials and systematic reviews will be needed to enhance evidence-based practice.

The present study identified only six RCTs that compared the fusion rates of different surgical approaches for instrumented lumbar spine fusion. There were four combinations of comparison as described above, and the body of literature was too small to perform quantitative analysis. Although some conclusions were possible through qualitative analysis, the clinical heterogeneity was problematic. For circumferential fusion, different approaches were used with PLF. Furthermore, the indications for fusion surgery and the type of graft material inserted into the disc space were not consistent. More importantly, the definitions of the radiological outcomes varied according to the trial, particularly for PLF.

This analysis had some limitations. Publication bias was unavoidable because the study selection was restricted to published peer-reviewed articles.[14] Furthermore, this study included only English-language journals. However, there is some controversy as to whether the language restriction would give rise to bias due to an overestimation of the reported treatment effect.[6,17] Another problem is that EMBASE was not included in the search strategy, which is in contrast to the recommendations of BRG.[10] EMBASE has a better coverage of European journals[18] but it focuses primarily on pharmacological publications.[19,20]

The current study only included instrumented fusions. Instrumented fusion has been reported to have a higher fusion rate than noninstrumented fusion.[21,22] Therefore, a meta-analysis or systematic review to compare the noninstrumented fusion rates according to the surgical approach may provide different results to the present findings. However, the heterogeneity between studies might have been more serious if this study had combined both instrumented and noninstrumented fusion studies. In addition, ALIF or PLIF using 'stand-alone' cages has been reported to have biomechanically lower stiffness than instrumented fusion, and is not considered to be a standard for spinal fusion.[1,23]

Whether osseous fusion rate correlates with the clinical outcome remains a controversial issue.[24,25] The clinical results were not analyzed systematically because the purpose of this study was to compare the fusion rates of different surgical approaches. Three studies reported that the clinical results correlated well with the fusion rates (Schofferman et al.,[8] Christensen et al.,[4] Kim et al.[7]). However, Fritzell et al.[5] reported that radiographic fusion did not significantly correlate with the clinical outcome. Inamdar et al.[11] recommended PLF over PLIF because of the simplicity of the procedure, lower complication rate and good clinical and radiological outcomes, even though both groups had fusion rates of 100%. In the study reported by Hallett et al.,[6] PLF was solid in more than 90% of stabilized patients and TLIF was even less clearly demonstrated than PLF. However, there was no significant difference between the groups in terms of the functional results.

The RCTs included in this study have some methodological flaws. Only three trials[4-6] described the adequate randomization method and its concealment. The blinding of patients and the outcome assessors was poor, even though the surgeon could not be blinded in surgical trials.[14] Most trials did not follow intention-to-treat principles except for one study, which can lead to a loss of randomization and possible inflation of the type-I error, or a false rejection of the null hypothesis.[6,13] Finally, the diagnostic criteria varied substantially from study to study as described above. Some studies included revision surgery and spondylolisthesis cases, but others did not. The level of the fused segments also varied. Only two trials[5,6] had more than six points according to the criteria list of BRG.[10,12] However, the lower-quality studies were not excluded because the results can be biased.

Another fundamental problem is that the presence of spinal instrumentation can make an evaluation of the fusion mass difficult, particularly in plain radiographs.[26-29] The posterolateral and interbody fusion mass may be obscured by pedicle screws and radioopaque interbody cage devices, respectively. In addition, the use of metal implants reduces the value of flexion and extension views by failing to show motion in the presence of pseudoarthrosis. Unfortunately, all the studies in this review used plain radiographs with or without flexion-extension views to determine the fusion status. However, no reported diagnostic technique, including fine-cut CT scans, has shown a high level of accuracy in predicting spinal fusion.[30]

In conclusion, one low quality RCT showed no difference in fusion rates between ALIF plus posterior transpedicular instrumentation and circumferential fusion, and PLIF and circumferential fusion.[7,8] There was moderate evidence suggesting no difference in fusion rate between PLF and PLIF.[7,11] The evidence on the fusion rate

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of circumferential fusion compared to PLF from qualitative analysis was contradictory.[4-7] However, a general statement could not be made because of the scarcity of data, heterogeneity of the trials included and some methodological defects.

The authors suggest that more RCTs in a homogeneous population be carried out to compare each single approach with circumferential fusion to determine whether a combined approach is necessary to improve the clinical results and fusion rate. A randomized comparison between single approaches, such as PLF vs. PLIF, ALIF vs. PLIF, or PLIF vs. TLIF, is also needed to provide an evidence-based rationale in the selection of appropriate fusion methods for spine surgeons.

CONFLICT OF INTEREST

The authors have no potential conflicts of interest relevant to this article.

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Anterior approaches to fusion of the cervical spine: a metaanalysis of fusion rates

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Object. Anterior cervical discectomy (ACD), ACD with interbody fusion (ACDF), ACDF with placement of an anterior plate system (ACDFP), corpectomy, and corpectomy with plate placement are used to fuse the cervical spine. The authors conducted a metaanalysis of studies published after 1990 in which fusion rates achieved with each procedure were reported for patients with degenerative disease at one, two, and three disc levels.

Methods. Twenty-one papers each included data on at least 25 patients. In each of the 21 studies the average clinical follow up was more than 12 months, and the results were evaluated according to radiographic evidence of fusion and delineated by the number of levels fused. Chi-square and Fisher exact tests were used for comparisons. The mean age of the patients was 46.7 years, 46.6% were female, and the mean follow-up period was 39.6 months. The studies included 2682 patients and the overall fusion rate was 89.5%. For single disc–level disease, fusion rates were 84.9% for ACD, 92.1% for ACDF, and 97.1% for ACDFP ($p = 0.0002$). For two disc–level disease, fusion rates were 79.9% for ACDF, 94.6% for ACDFP, 95.9% for corpectomy, and 92.9% for corpectomy with plate placement ($p = 0.0001$). For three disc–level disease, fusion rates were 65.0% for ACDF, 82.5% for ACDFP, 89.8% for corpectomy, and 96.2% for corpectomy with plate placement ($p = 0.0001$). The use of anterior plates significantly improved fusion for one-level ($p < 0.0001$), two-level ($p < 0.0001$), and three-level ($p < 0.05$) ACDF. There was no significant difference in fusion rates between two-level ACDF and corpectomy with plate placement.

Conclusions. The anticipated fusion rate is one of several factors that may guide surgical decision making. Anterior cervical decompression and fusion results in high fusion rates. The results of the authors' study show that regardless of the number of levels fused, the use of an anterior cervical plate system significantly increases the fusion rate. For two-disc–level disease, there was no significant difference between ACD with a plate system or corpectomy with a plate system. For three-disc–level disease, however, the evidence suggests that corpectomy with plate placement is associated with higher fusion rates than discectomy with plate placement.

Key Words • **anterior cervical discectomy and fusion** • **corpectomy** • **cervical plate** • **fusion rate**

Anterior decompression and fusion of the cervical spine have become important in the treatment of degenerative cervical disease that causes myelopathy and radiculopathy. Techniques include ACD, ACDF, ACDFP, vertebral corpectomy, and corpectomy with placement of an anterior plate. The choice of technique depends on the number of levels of disease and the particular diagnosis. The authors of some studies[30] have cited graft collapse and settling as reasons for the use of a plate, whereas others[5,11,17] have cited enhancement of solid fusion, thus raising the question of whether plate placement truly enhances the fusion rate. Additionally, controversy exists about the effectiveness of ACDF versus corpectomy for the treatment of multilevel disease. In approaching surgical management decisions, it is important to understand relative fusion rates as one comparative outcome measure. When treatment options are presented to patients, the relative risks and benefits of each procedure must be explained. While there is a substantial amount of literature on different fusion procedures for the cervical spine, little direct comparison has been made for different levels of surgery (one-level, two-level, and three-level procedures). We compared fusion rates achieved with different anterior cervical fusion procedures by the number of levels fused through a metaanalysis of published literature for the period from 1990 to 2005 in an effort to provide some aggregate benchmarks for clinical practice.

Abbreviations used in this paper: ACD = anterior cervical discectomy; ACDF = ACD and fusion; ACDFP = ACDF and placement of an anterior plate system.

Clinical Material and Methods

A search of the PubMed database was conducted in May 2005 to screen for fusion outcome–related studies of cervical decompression and fusion published after 1990. The search terms included anterior cervical decompression, ACDF, corpectomy, fusion rate, cervical plate, and cervical discectomy. The inclusion and exclusion criteria for each

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study are shown in Table 1. Of 49 papers published from 1990 to 2005 on anterior cervical fusion, 21 met inclusion criteria for our study.

Primary outcome was fusion rate as defined by each study. Although the authors of the 21 studies did not use a uniform methodology for assessing fusion, there were several common principles. Fusion was assessed at least by plain anteroposterior and lateral radiographs, with most studies also using flexion–extension views. Visualization of trabecular bridging across the bone–graft interface, absence of radiolucent gaps between the endplate and graft, and restriction of motion (to 0–2 mm) of the fused-level spinous process on flexion–extension constituted common operational principles of fusion cited in the literature.

Patient demographic data and epidemiological details from each study were also recorded and analyzed. The number of fused levels was noted for each study group, and analyses were conducted to compare procedures for different numbers of levels. For comparison by number of levels, "level" was defined by vertebral level for corpectomy and by disc level for discectomy. For example, a C4–5, C5–6 ACDF would be a two-level procedure, whereas a C-5 corpectomy would be a one-level procedure, although they both involve surgical decompression from C4–5 to C5–6. Statistical analyses included use of contingency tables, with chi-square and Fisher exact testing used for group and pairwise comparisons, respectively.[1] Probability values less than 0.05 were considered significant. A multivariate analysis controlling for factors known to affect fusion rates, such as age, smoking status, comorbidities, and the use of postoperative bracing, would have been desirable but was not possible because this information was not available for all studies.

TABLE 1

Inclusion and exclusion criteria for published studies

Inclusion Criteria	Exclusion Criteria
total no. of patients >25	trauma
mean clinical follow up ≥12 mos	neoplastic disease
radiographic evidence of spine fusion	posterior fusion
delineation of fusion rates by no. of levels fused	"redo" operations
1–3 disc levels fused	fusion augmentation*

* For example, by means of bone morphogenetic protein.

Results

Study Information

The 21 studies that met the criteria for inclusion in the metaanalysis are summarized in Table 2.[2,4–6,9–15,17–20,22,24,26,27,30,31] Four of the studies were prospective randomized trials. Two evaluated the necessity of fusion in patients undergoing ACD for single-level disease.[9,26] In one study the authors compared posterior cervical foraminotomy, ACD, and ACDF for single-level cervical disc disease.[31] Also shown are the types of graft and plate materials used. Of note, authors of several reports did not include some details regarding fusion materials, and authors of some studies did not separate fusion outcomes by type of graft or plate used. In one study, outcomes were compared for patients undergoing one-level ACDF with and without a titanium hydroxyapatite-coated fusion cage.[13] There were 364 patients who were involved in randomized control trials.[9,13,26,31]

Patient Demographics

A total of 2682 patients were included from the 21 studies. For the studies overall, the mean age was 46.7 years (range 40–64.9 years), and 46.6% of patients were female (range 30.8–60.0%). The mean follow-up period for the 21 studies was 39.6 months postoperatively (range 14–253 months). The most commonly treated level was C5–6, with reported symptoms including neck pain, radiculopathy, and myelopathy. The most common operation was a one-level ACDF (1231 cases), and the least common was a three-level ACDFP (40 cases).

Fusion Rates

The overall fusion rate for all 2682 patients was 89.5% (Table 3). For single disc–level interventions (Fig. 1), group analysis demonstrated an overall significant difference between groups ($p = 0.0002$). In pairwise comparisons, there was a statistically significant difference between ACDF and ACDFP for one-level disease (92.1% compared with 97.1%; $p < 0.0001$).

For interventions for two disc–level disease (two-level ACDF, two-level ACDFP, one-level corpectomy, and one-level corpectomy with plate placement; Fig. 2), there was a significant difference among groups ($p < 0.0001$, chi-square test). Pairwise comparisons of ACDFP and corpectomy with plate placement revealed no statistically significant difference between the two fusion rates. However, pairwise comparison of ACDF and ACDFP revealed a significant difference ($p < 0.0001$).

For interventions for three disc–level disease (three-level ACDF, three-level ACDFP, two-level corpectomy, and two-level corpectomy with plate placement; Fig. 3), there continued to be an overall difference in fusion rate among groups ($p < 0.0001$, chi-square test). Pairwise comparisons of ACDF and ACDFP again demonstrated a significant difference ($p = 0.05$). Although the two-tailed Fisher exact test demonstrated no significant difference in fusion rate between ACDFP and corpectomy with plate placement, use of a one-tailed test demonstrated a significantly higher fusion rate for corpectomy with plate placement than for ACDFP ($p = 0.03$).

Discussion

Degenerative diseases of the cervical spine, including herniated intervertebral discs, cervical spondylosis, ossification of the posterior longitudinal ligament, and cervical stenosis, can result in significant radiculopathy, myelopathy, or both. Surgical treatment options include a number of anterior approaches, but there is no universal consensus on the average fusion rate for each procedure. One-level ACDFs with and without plate placement have yielded successful results since first described by Bailey and Badgley,[3] and refined by Cloward[7,8] and Robinson.[25] Fusion rates for one-level procedures are almost uniformly in the range of

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TABLE 2

Summary of studies included in metaanalysis

Authors & Year	Type	Class	No. of Patients		Graft Type	Plates (Manufacturer)
			Total	Available for Evaluation		
Caspar et al., 1998	retrospective review	III	356	346	allograft & autograft	Caspar Bicortical (Aesculap), Cervical Spine Locking Plate systems (Synthes), Orion (Medtronic Sofamor Danek)
Cauthen et al., 1998	retrospective review	III	348	345	autograft or allograft	none
Gore & Sepic, 1998	retrospective review	III	68	50	iliac or tibial autograft	none
Savolainen et al., 1998	prospective, randomized trial	I	91	91	iliac autograft	Caspar (Aesculap)
Dowd & Wirth, 1999	prospective, randomized trial	I	84	62	iliac autograft	none
Majd et al., 1999	prospective review	III	34	22	vertebral autograft, titanium cage	not detailed
Martin et al., 1999	retrospective review	III	317	287	fibular allograft	none
Hacker et al., 2000	prospective, randomized trial	I	488	180	vertebral autograft, titanium cage	none
Wirth et al., 2000	prospective, randomized trial	I	72	31	iliac autograft	none
Wang et al., 2001	retrospective review	III	59	59	iliac autograft	not detailed
Agrillo et al., 2002	retrospective review	III	45	45	carbon fiber cage w/ hydroxyapatite	none
Edwards et al., 2002	matched cohort study	II	26	11	strut allograft and autograft	not detailed
Hilibrand et al., 2002	retrospective review	III	190	168	iliac autograft or strut allograft and autograft	not detailed
Kaiser et al., 2002	retrospective review	III	540	520	cortical allograft	Orion (Medtronic Sofamor Danek), Codman (Johnson & Johnson), Atlantis (Medtronic Sofamor Danek)
Epstein, 2003	retrospective review	III	42	42	iliac autograft or fibular allograft in 3 patients	ABC plate (Aesculap)
Rieger et al., 2003	prospective review	III	27	24	vertebral autograft, titanium cage	Orion (Medtronic Sofamor Danek)
Balabhadra et al., 2004	retrospective review	III	98	98	allograft	ABC plate (Aesculap)
Nirala et al., 2004	retrospective review	III	220	183	iliac autograft	none
Park et al., 2004	retrospective review	III	26	26	fibular allograft, 1 iliac autograft	Macropore (MacroPore, Inc.)
Sevki et al., 2004	retrospective review	III	26	14	vertebral autograft, titanium cage	not detailed
Hwang et al., 2005	prospective review	III	78	78	vertebral autograft, titanium cage	none
			3235	2682		

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TABLE 3

*Cumulative fusion rates for each surgical procedure**

Type of Surgery	Outcome (no. of procedures)		Total (no. of procedures)	Fusion Rate (%)
	Fusion	Pseud-arthrosis		
1-disc–level procedures				
1-level ACD	62	11	73	84.9
1-level ACDF	1134	97	1231	92.1
1-level ACDFP	329	10	339	97.1
2-disc–level procedures				
2-level ACDF	337	85	422	79.9
2-level ACDFP	174	10	184	94.6
1-level CORP	70	3	73	95.9
1-level CORPP	52	4	56	92.9
3-disc–level procedures				
3-level ACDF	80	43	123	65.0
3-level ACDFP	33	7	40	82.5
2-level CORP	79	9	88	89.8
2-level CORPP	51	2	53	96.2
total	2401	281	2682	89.5

* CORP = corpectomy; CORPP = CORP with plate placement.

95 to 100%. However, multilevel procedures still are associated with high rates of pseudarthrosis, mechanical failure, and/or postoperative kyphosis. The decision to perform a multilevel ACD rather than a corpectomy is based on the degree, location, and extent of cervical spinal cord compression; the presence of existing cervical deformity; the risk of mechanical failure; and the expected fusion rate. This last factor is controversial; some authors[14,20] have argued that a one-level anterior cervical corpectomy may result in higher fusion rates than a two-level ACDF when no anterior plate is used. The authors of a recent study[30] comparing one-level corpectomy and two-level ACDF with cervical plate placement did not find a difference in fusion rates. Alternatively, cervical corpectomies have been associated with relatively high mechanical failure rates in patients and in cadavers,[16,29] especially when fibular strut allograft was used.[21] Recent biomechanical data suggest that segmental plate fixation is superior to end-construct plate

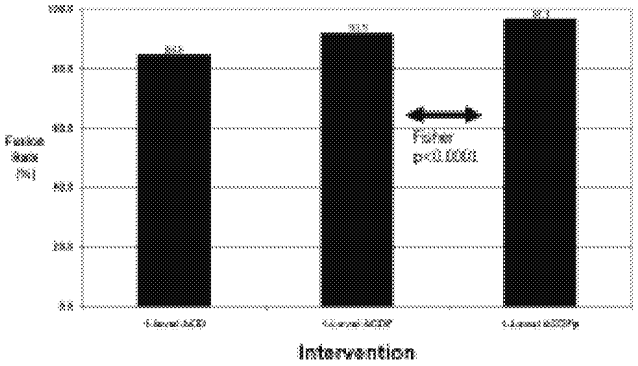

FIG. 1. Bar graph illustrating fusion rates for surgical interventions involving single disc levels. Note that the fusion rate for ACD alone (without an interbody fusion graft or plate placement) was 84.9%.

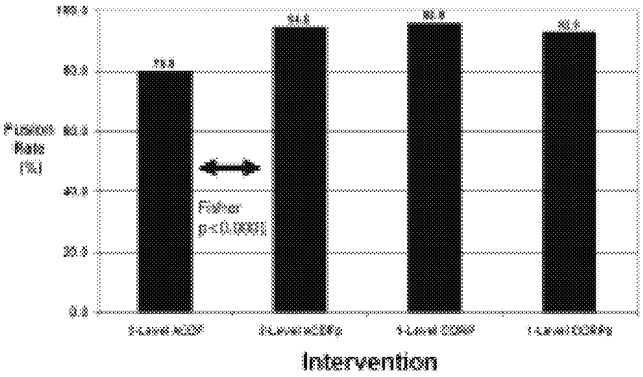

FIG. 2. Bar graph illustrating fusion rates for surgical interventions involving two disc levels. There were no significant differences between ACDFP, corpectomy (CORP), and corpectomy with plate placement (CORPp) in pairwise comparisons.

fixation after multilevel cervical corpectomies.[23,28] Against this background we used published data to develop a metaanalysis for estimating fusion rates for each type of cervical decompressive procedure by the number of levels fused. Overall, anterior approaches are associated with a relatively high fusion rate (89.5%) regardless of the number of levels fused. Thus, as a set of procedures, ACDF results in a relatively high fusion rate.

For single disc–level disease, ACD alone results in a significant fusion rate (84.9%); as would be expected, the addition of allograft and anterior plate increases the fusion rate. For two- and three disc–level disease ACDFP and corpectomy with plate placement are relatively comparable. There is some evidence that corpectomy with plate placement may be superior to ACDFP for three disc–level disease, although the smaller numbers of patients who underwent these procedures for three level–disease (53 and 40, respectively) and confounding variables may limit the statistical analysis. The use of a variety of outcome measures precluded statistical analysis of clinical outcomes. A multivariate analysis controlling for factors that have a known effect on fusion rates, such as age, smoking status, comorbidities, and the use of postoperative bracing, would have been desirable but was not possible because this information was not available for all studies.

There are limitations to this study that may restrict the conclusions drawn from the statistical analysis. First, as a metaanalysis, this study is subject to publication bias; only published data may be analyzed, and conclusions depend on the accuracy of published studies to reflect the practices and outcomes in the general population. Although there is no method to detect the extent of the effect of this limitation, large sample sizes aid in reducing the overall effect on the conclusions. Second, the quality of assessment of fusion status is an important element for defining "successful" fusion. There are no universal standards for radiographic evaluation of fusion status in the cervical spine. The authors of the studies included in this metaanalysis used standards with several common elements, including lack of movement on flexion/extension x-ray films and bridging of bone across the fusion mass–bone interspace. These standards have yet to be fully tested and validated, but their common employment in the included studies re-

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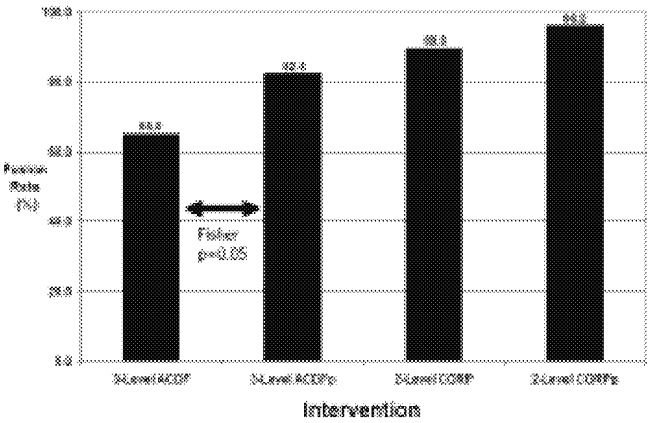

FIG. 3. Bar graph illustrating fusion rates for surgical interventions involving three disc levels. Corpectomy with plate placement resulted in the highest total fusion rate (96.2%).

duces the variability and potential confounding effect of assessment of fusion. Third, the majority of studies included for analysis represent Class III data. Although four studies were prospective, randomized trials, most data included for analysis came from case series. Although the use of Class III data does reduce the overall legitimacy of the metaanalysis, it does not preclude its use for analytical understanding of fusion rates in the cervical spine. Fourth, the types of fusion grafts and plate systems were not homogeneous. The lack of information in some studies regarding grafts and plate systems and respective outcomes delineated by type of system precluded subgroup analysis by graft and plate system. Thus, it is unclear what effect different fusion materials have on fusion rates at different levels. Finally, clinical outcomes were not analyzed due to variability in outcome standards, lack of some outcome information in some studies, and lack of universal assessment tools for outcome evaluation. Thus, it is important to note that, even though fusion rates are important, their analysis in this study is not intended as a surrogate for comparison of clinical outcomes. Although this study is successful in providing some aggregate benchmarks for fusion in anterior cervical procedures, additional studies are required to fully assess clinical outcomes of different methods of anterior cervical fusion. Specifically, we suggest that a set of fusion-related outcomes be uniformly reported so that data may be compared and understood in relationship to previously published benchmarks. Fusion rates should be reported according to graft and plate system used. Information regarding intervening screws for multilevel plate systems, sagittal angles, and uniform systematic clinical outcome scales would enhance the understanding of the relative success of each fusion procedure.

Conclusions

Anterior cervical decompression and fusion results in relatively high fusion rates. Regardless of the number of levels fused, the use of an anterior cervical plate system significantly increases the fusion rate. A metaanalysis of the literature provides some fusion rate benchmarks for practitioners. For two disc–level disease, there was no significant difference between ACD with plate placement or corpectomy with plate placement. For three disc–level disease, the evidence suggests that corpectomy and plate placement may be superior to ACDFP; although the limitations of the study prevent the application of this finding to general practice, the finding supports further research to address this question.

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A prospective randomized comparison of 270 degrees fusions to 360 degrees fusions (circumferential fusions)

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Affiliations
PMID: 11413440 DOI: 10.1097/00007632-200105150-00019

Abstract

Study design: Prospective randomized comparison of anterior lumbar interbody fusion (ALIF) plus transpedicular instrumentation plus posterolateral fusion (PLF) (360 degrees fusion) to ALIF plus transpedicular instrumentation without PLF (270 degrees fusion).

Objectives: To compare the clinical outcomes, costs, and utilization of health resources of 360 degrees versus 270 degrees fusions.

Background: The 360 degrees fusion is effective, but its costs and utilization of health resources are high. The PLF often resorbs and may not be necessary.

Methods: Before and after surgery pain was measured by the Numerical Rating Scale (NRS), and function was measured by the Oswestry Low Back Disability Index (OSI). Costs were calculated by billing records. Operating times, blood loss, and hospital stays were measured at the time of hospital discharge.

Results: There were 48 patients: 21 women and 27 men. Mean age was 42 years. Follow-up averaged 35 months (range 24-45 months). In both 360 degrees and 270 degrees fusions, there were significant improvements in NRS and OSI, and the percentage of solid ALIF was high. Only 14% of PLF appeared solid bilaterally and 18% appeared solid on one side only. There were no significant differences in changes in NRS, changes in OSI, or percentage solid ALIF between the 360 degrees and 270 degrees fusions. However, the 270 degrees fusion group had significantly less blood loss, shorter operative times, shorter hospital stays, and lower professional fees, and although hospital charges were lower, this difference was not significant.

Conclusion: Both the 360 degrees and 270 degrees fusions significantly reduce pain and improve function, and there are no significant clinical differences between them. However, there were shorter operating times, less blood loss, lower costs, and less utilization of health care resources associated with the 270 degrees fusions.

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Chronic Low Back Pain and Fusion: A Comparison of Three Surgical Techniques

A Prospective Multicenter Randomized Study From the Swedish Lumbar Spine Study Group

Peter Fritzell, MD,* Olle Hägg, MD,† Per Wessberg, MD,† Anders Nordwall, MD, PhD,† and the Swedish Lumbar Spine Study Group‡

Study Design. A multicenter randomized study with a 2-year follow-up period and an independent observer was conducted.

Objective. To compare three commonly used surgical techniques to achieve lumbar fusion primarily in terms of their ability to reduce pain and decrease disability in patients with severe chronic low back pain.

Summary of Background Data. Lumbar fusion can be used to reduce pain and decrease disability in patients with chronic low back pain, and different surgical techniques are available. The reported results after fusion surgery vary considerably, but most studies are retrospective and/or performed on heterogeneous patient groups. Spine surgeons commonly use the techniques presented in this report. However, in the absence of randomized trials it is difficult to know whether any one of them is better than the others for these patients.

Methods. From 1992 through 1998, 294 patients referred to 19 spinal centers were blindly randomized into four treatment groups: three surgical groups (n = 222) and one nonsurgical group (n = 72). The sociodemographic and clinical characteristics did not differ among the groups. Eligibility included patients 25 to 65 years of age with therapy-resistant chronic low back pain that had persisted for at least 2 years and radiologic evidence of disc degeneration (spondylosis) at L4–L5, L5–S1, or both. Only patients randomized to one of three surgical groups were analyzed in the current study: Group 1 (posterolateral fusion; n = 73), Group 2 (posterolateral fusion combined with variable screw placement, an internal fixation device; n = 74), and Group 3 (posterolateral fusion combined with variable screw placement and interbody fusion; n = 75). The "circumferential fusion" in Group 3 was performed either as an anterior lumbar interbody fusion (n = 56) or as a biomechanically similar posterior lumbar interbody fusion (n = 19). The groups were composed of 51%, 58%, and 40% men respectively, and the respective mean ages were 44, 43, and 42 years. The patients had experienced low back pain for at least 2 years (mean, ≈8 years). They had been on sick leave for approximately 3 years. Pain was measured by a visual analog scale, and disability was assessed by the Oswestry Low Back Pain Questionnaire, the Million Visual Analogue Score, and the General Function Score. Depressive symptoms were measured by the Zung Depression Scale. The global overall rating of the result was assessed by the patient and an independent observer after 2 years. Hospitalization data including operation time, blood loss, blood transfusion, and days of hospitalization in connection with surgery were reported, along with complications and the fusion rate. Records from the Swedish Social Insurance Board providing information on sick leave and economic compensation for Swedish residents were used to evaluate the patients' work status.

Results. An independent observer examined 201 (91%) of 222 patients after 2 years, after 18 "group changers" and 3 dropouts had been excluded from the analyses. All surgical techniques were found to reduce pain and decrease disability substantially, but no significant differences were found among the groups. In all three groups, the patients rated the overall outcome similarly, as did the independent observer. The more demanding techniques in Groups 2 and 3 consumed significantly more resources in terms of operation time, blood transfusions, and days in hospital after surgery. The early complication rate was 6% in Group 1, 16% in Group 2, and 31% in Group 3. The fusion rate, as evaluated by plain radiograph, was 72% in Group 1, 87% in Group 2, and 91% in Group 3.

Conclusions. All the fusion techniques used in the study could reduce pain and improve function in this selected group of patients with severe chronic low back pain. There was no obvious disadvantage in using the least demanding surgical technique of posterolateral fusion without internal fixation. [Key words: chronic low back pain, degenerative disc disease, functional outcome, lumbar spinal fusion, prospective randomized multicenter clinical study, spondylosis] **Spine 2001;27:1131–1141**

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Device status category: 2.
Conflict of interest category: 16.

During recent decades, surgical fusion of the lumbar spine has been performed increasingly on patients with chronic low back pain (CLBP) of "unknown etiology."[13,37] However, wide differences in the rate of low back surgery exist among different countries and also between areas within countries.[1,7,10] Consequently, the indications for surgical treatment of CLBP without spe-

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cific radiographic changes are controversial.[48,49] However, in a previous report, the Swedish Lumbar Spine Study Group has shown the efficacy of lumbar fusion, as compared with commonly used nonsurgical therapy, in reducing pain and decreasing disability in a selected group of patients with CLBP.[20]

Different surgical techniques can be used to achieve lumbar fusion.[1,30,36,62] If the source of pain is believed to be the facet joints,[44] it seems logical to use posterolateral fusion,[60] in which bone is placed over decorticated transversal processes and these facet joints.[61] If the disc[9,19] is suspected instead, it seems reasonable to remove this structure and replace it with a bone transplant, using either posterior lumbar interbody fusion (PLIF),[8,56] or anterior lumbar interbody fusion (ALIF).[24,29,53] If pain is thought to be generated from both these structures, or if the surgeon strives for maximum initial stability and bone transplant area, hypothetically it should be better to fuse from both the behind and the front to create a "circumferential" (360°) fusion.[12,22,31,38,39,51] These techniques may or may not be supplemented by internal fixation, aiming at immediate stability, which probably increases the fusion rate[5,23,40,50] and hopefully makes the rehabilitation process easier for the patient. However, the use of an internal fixation device increases the complication rate and is controversial in this patient population[4,47,63].

It has been shown that all fusion techniques used in the current study have the potential to reduce pain, decrease disability, and create an osseous fusion in patients with CLBP.[39,50,53,54,56] However, the reported results vary considerably among different studies,[23,58] and the complication rate after fusion surgery in the lumbar spine is not negligible.[11,15] A report from a recent Cochrane literature review study by Gibson et al,[23] showed that internal fixation might promote fusion, but that this does not seem to correlate well with clinical outcome. The lack of correlation between osseous fusion and clinical result was demonstrated in three recent randomized trials.[18,43,57] Furthermore, none of these studies demonstrated a significant difference in fusion rate related to internal fixation.

The Swedish Lumbar Spine Study Group has shown that lumbar fusion in selected patients with CLBP gives superior results in terms of reducing pain and disability, as compared with nonspecific nonsurgical methods.[20] The current study compares the three methods used for achieving lumbar fusion in that study.

Methods

This study reports both the clinical and technical outcomes[25] after 2 years in 201 patients, ages 25 to 65 years, who underwent lumbar fusion because of severe and therapy-resistant CLBP. The patients, referred by primary care physicians and other clinicians to 19 orthopedic departments participating in the Swedish Lumbar Spine Study from 1992 through 1998, were randomly allocated to three surgical groups. Both the inclusion criteria and the procedure for randomization presented in this report were described more fully in a previous report comparing surgical fusion with nonsurgical treatment.[20] The patients were informed that, as far as was known, no one treatment method was superior to any other. Those choosing to participate completed self-administered questionnaires covering subjective, clinical, paraclinical, and sociodemographic data.

The ethics committees at all the participating universities approved the study. All the patients gave informed consent, and all pretreatment questionnaires and protocols were completed before randomization.

Inclusion Criteria. The following were required of all patients eligible for participation in this study:

Age of 25 to 65 years

Severe CLBP assessed by the treating surgeon as emanating from L4 to L5, L5–S1, or both, unaccompanied by any dominant leg pain component

Pain duration of at least 2 years and no obvious ongoing psychiatric illness

Sick leave or equivalent pain and disability over the preceding year that had not responded to conservative treatment and life adjustments

Degenerative changes (spondylosis) shown on plain radiographs, computed tomography scan, and/or magnetic resonance imaging

No specific radiologic findings such as isthmic spondylolisthesis, spinal stenosis, new or old fractures, infection, inflammatory process, or neoplasm

Disc herniation if clinical signs of nerve root compression were absent

No previous spine surgery except for successful removal of a herniated disc more than 2 years preceding entrance to the study and no persistent nerve root symptoms (n = 37).

For inclusion in the study, two spine surgeons needed to agree independently that a patient had met the eligibility and inclusion criteria. Diagnostic procedures such as discography, facet blocks, external fixation, and external support (corset) were used in subgroups of the study population. The feasibility and prognostic value of these methods, which often are discussed but not routinely used, is reported separately.

Randomization. Altogether, 294 patients met the inclusion criteria. These patients were randomized blindly into one of four treatment groups using a computer-generated random list, with the individual numbers kept in sealed envelopes outside the participating departments. One group included only nonsurgical treatment (n = 72). A comparison between surgical and nonsurgical treatment is presented in a separate article.[20] The remaining 222 patients were allocated to the following groups: Group 1 (posterolateral fusion[60] without internal fixation; n = 73), Group 2 (posterolateral fusion combined with variable screw placement and[55] an internal fixation device; n = 74), and Group 3 (posterolateral fusion combined with variable screw placement and interbody fusion, a "circumferential" [360°] fusion; n = 75).[38] Fusion in Group 3 was performed as either an ALIF[29] (n = 56) or a biomechanically similar PLIF[8] (n = 19). These subgroups were referred to as Group 3ALIF and Group 3PLIF.

Surgical Procedures. The different procedures were performed by 26 experienced spine surgeons from 19 orthopedic departments. In 1992, all these surgeons routinely performed

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instrumented posterior fusions, and the technical aspects of the different procedures were discussed thoroughly to ensure, as far as possible, that the same routines would be followed at the different centers. No patient underwent surgery by a surgeon not experienced with the technique.

The patient was positioned according to local preferences in a prone position. Autologous bone harvested from the iliac crest was used in all cases.[34] In Group 1, bone was placed on decorticated transverse processes and facet joints bilaterally. In Groups 2 and 3, the fusion was supplemented with the variable screw placement, a device consisting of pedicle screws and open bendable plates (DePuy Acromed, Raynham, MA). Pedicle screw insertion was guided by imaging, and plates were applied according to the technique of Steffee et al.[55]

The interbody procedure in Group 3 included either ALIF or PLIF, according to the preference of the surgeon. In addition to the posterolateral bone transplant, as much disc material as possible was removed between the vertebral bodies both laterally and centrally, and the endplates were prepared using the variable screw placement instruments to create an adequate subchondral support for the grafts. The tricortical bone blocks were inserted in slight distraction and compressed during the instrument-locking procedure. No spacer was used in any of the cases, and patients in all the groups were fused *in situ* with no intention of decompression. When ALIF was used, the patient underwent surgery from both the back and the front as part of the same procedure.

After surgery, the patients were rehabilitated according to local preferences. As a rule, this meant early ambulation, usually within a couple days. If no internal fixation had been used, the patients wore a rigid plastic corset day and night for 5 months after surgery.[33] Otherwise, they wore reinforced canvas for the same period.

Collected Data and Outcome Measures. Pain, disability, global self-rating by the patient, and return to work were the primary outcome measures in the study, although other measurements also were used.[20] Both self-administered questionnaires and examination protocols were used both when data were collected before randomization and after 2 years. Complications and pain also were recorded after 6 and 12 months.

The following data were collected as described:

Sociodemographic characteristics were collected using questionnaires, but files from the Swedish Social Insurance Board were used for work status (Table 7).

Clinical characteristics were assessed using standardized examination protocols including, among others, mobility, walking and moving capability, reflexes, muscular strength, and a pain provocation test aimed at reproducing the patients problems by pressing on the spinous processes in the lumbar region (springing test).

Pain in the back and leg was measured using a vertical visual analogue scale,[32] with options ranging from 0 to 100, in which 100 reflected the worst pain imaginable.

Disability was measured using three different disease-specific health scores: the Oswestry Low Back Pain Questionnaire,[16] the Million Score, [41] and the General Function Score (GFS).[27] All instruments had ranges from 0% to 100%, with 100% reflecting maximum disability.

Depressive symptoms were assessed using the Zung Depression Scale,[64] which had a range from 0% to 100%.

Overall result according to the patient was assessed by the patient's response to the following: Compared with before treatment my back problems are "much better," "better," "unchanged," or "worse."

Overall result according to the independent observer was assessed according to the following well-described ordinal scale: excellent (no pain, no functional restrictions, no analgesics), good (sporadic pain, slight restriction of function, occasional analgesics), fair (moderate pain, moderate restriction, no sports, daily analgesics), or poor (moderate daily or occasional severe pain, function restricted in activities of daily living, use of strong analgesics).

Hospitalization data, which included operation time, blood loss, blood transfusion, and days in hospital in connection with surgery, were obtained from the study protocols and hospital records.

Complications were classified as major and minor, early and late. This information was obtained from the study protocols and hospital records, including surgical protocols.

Radiographic fusion rate after 2 years was assessed by an experienced radiologist, who was blinded to the clinical outcome. Both the posterolateral and the interbody fusion areas were assessed on a 3-point scale: 1 (definite fusion), 2 (uncertain fusion), or 3 (definite pseudarthrosis). Anteroposterior and lateral radiographs of the lumbosacral region were used in all cases. Healed posterolateral fusion was defined as trabeculae crossing the graft–transverse process interface on both sides, with evidence of increasing density of the graft with cortication. In the interbody procedure, fusion was defined as trabeculae crossing the graft–vertebral body interface on both sides of the graft. In the 360° group, interbody fusion that healed convincingly was assumed to be sufficient. Fusion was accepted only if all levels of attempted fusion were assessed as fused. Intervertebral distances were measured before and 2 years after surgery, using a common but approximate method. On lateral radiographic exposures, the radiologist measured the intervertebral distance at both the front and back, using the mean of these distances to estimate the total disc height.[2] The change in height was presented as a median value for the interbody (ALIF/PLIF) group.

Work status was reported at baseline and after 2 years, using files from the Swedish Social Insurance Board. Patients receiving a full-time disability pension at baseline were excluded from the analysis.

Results from previous surgery for disc herniation in the subgroup of patients who had undergone a previous successful surgery for disc herniation more than 2 years before randomization (n = 37) were reported.

Results from interbody fusion in the subgroups of Group 3 (ALIF and PLIF) were reported.

Follow-up Evaluation. Pain and complications were measured after 6 and 12 months, in addition to the 2-year follow-up assessment. This was done partly for ethical reasons as a monitor for unexpected results in any group, in which case the study could have been stopped. At 2 years after the onset of treatment, the data collection procedures before randomization were repeated using the same questionnaires and protocols.

"Group Changers" and Dropouts. "Group changers" were patients who would not comply with the randomization, but changed from surgical to nonsurgical treatment or *vice versa*. "Dropouts" were patients who could not be followed up after 2 years for various reasons. Group changers and dropouts were

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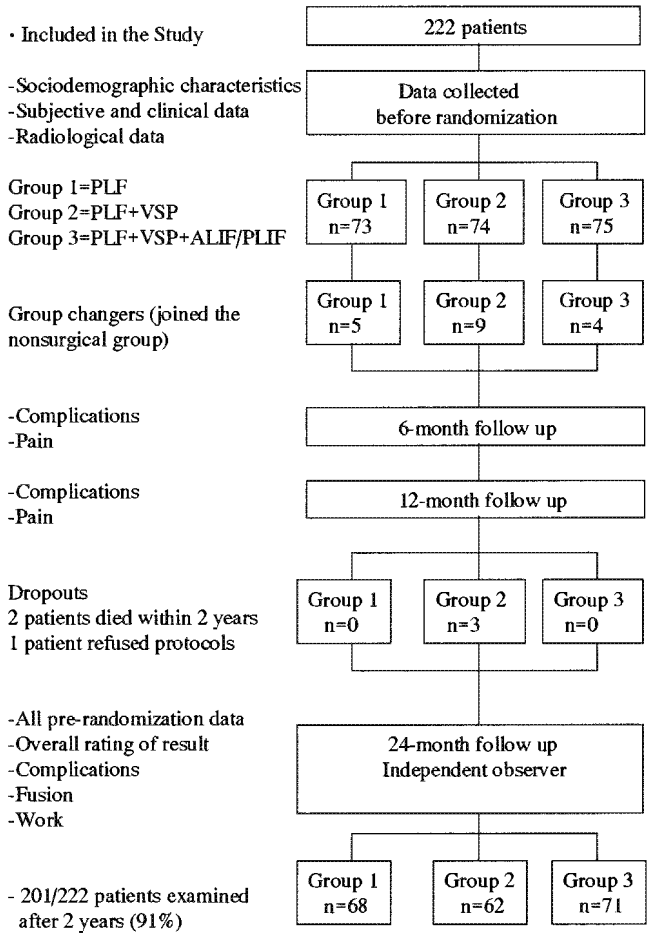

Figure 1. Flow diagram for surgically treated patients.

excluded from the analyses because the authors did not believe any purpose was served by performing an intention-to-treat analysis between the surgical groups, as was done when surgery was compared with nonsurgical treatment[20] (Figure 1).

Statistical Methods. All data were entered into the SPSS statistical program, Version 10.0. Because most variables were basically ordinal data, and because continuous variables (visual analog scales) were not exactly normally distributed, nonparametric methods were used to calculate statistical significance. The Kruskal-Wallis test, the Mann-Whitney test, or Fisher's exact test were considered appropriate for testing the differences among the groups. The Wilcoxon signed rank test was used for differences within the groups. Spearman's rank correlation test was used to test the correlation between variables. Two-tailed tests were used. Because of multiple comparisons and a risk of random significance, the risk level was set at 0.01 rather than 0.05. All test results lower than 0.01 were therefore considered significant at the 5% level.

Results

After 2 years, 201 (91%) of the 222 patients followed up by an independent observer were included in the analyses. A total of 18 group changers from surgical to nonsurgical treatment (five in Group 1, nine in Group 2, four in Group 3) and three dropouts from Group 3 were excluded. Consequently, from 1992 through 1998, the number of patients included in the analyses for each group were as follows: 68 patients in Group 1, 62 patients in Group 2, and 71 patients in Group 3 (Figure 1).

Sociodemographic Characteristics

The three groups were similar in terms of sociodemographic characteristics, but there was a tendency toward more women ($P = 0.089$), fewer married or domestic partners ($P = 0.062$), and more comorbidity ($P = 0.092$) in Group 3.

Clinical Characteristics

The clinical characteristics of the entire study population, reported in detail elsewhere,[20] did not differ among the three surgical groups.

Pain

Back pain was reduced significantly in all three surgical groups (Table 2). In the longitudinal analysis, back pain decreased significantly at all measuring points, as compared with the baseline values, but pain increased in all groups between 12 and 24 months (Figure 2).

Disability

A highly significant decrease in disability was observed in all the surgical groups, but no significant differences were found between the groups (Table 2).

Depressive Symptoms

No difference in depressive symptoms existed among the groups at the time of randomization. All the groups had fewer signs of depressive symptoms after 2 years, but there were no differences among the groups (Table 2).

Overall Rating of the Result by the Patients and the Independent Observer

Between 60% and 68% of the patients in the three groups rated the overall treatment result as "much better" or "better" (Table 3). In Group 1, the independent observer assessed the result as "excellent" or "good" in 41%, "fair" in 37%, and "poor" in 22% of the patients. The corresponding figures were 50%, 27%, and 23% in Group 2, and 46%, 33%, and 21% in Group 3. These differences were not significant.

Hospitalization

The more technically demanding surgical techniques consumed the most resources. Patients in Group 1 spent fewer days in the hospital, had the shortest operation time, and needed almost no blood transfusions (Table 4).

Complications

In these analyses, the patients that changed from nonsurgical to surgical treatment (n = 7) and the dropouts (n = 3) were included, for a total of 211 surgically treated patients. There were no deaths in connection with surgery, and most early complications were managed with few sequelae for the patient.

The complication rate increased with rising technicality of the procedures (Table 5). Altogether, 18% (37/211) of the surgically treated patients experienced an early complication, and 6% (13/211) had a late compli-

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Table 1. Sociodemographic Characteristics at the Time of Randomization*

	Group 1 (n = 73)		Group 2 (n = 74)		Group 3 (n = 75)	
Age (range)	44 (25–62)		43 (25–65)		42 (28–59)	
Mean pain duration: years (range)	7.8 (2–32)		7.3 (2–33)		8.2 (2–34)	
Mean time of sick leave: years (range)	3.2 (0.1–18)		3.1 (0.1–15)		3.2 (0.1–15)	
	%	Missing (n)	%	Missing (n)	%	Missing (n)
Men	53.4		60.8		40.0	
Married/domestic partner	83.3	1	80.8	1	68.0	
Comorbidity	32.9	3	34.7	2	49.3	2
Smoking	38.9	1	43.1	2	40.0	
Earlier (>2 years) successful removal of herniated disc	24.7		18.1	2	13.3	
Employed	74.0		75.3	1	72.0	
Changed job because of back problems	27.4		23.9	3	36.5	1
On full-time sick leave because of back problems	58.5	1	52.1	1	65.8	3
Disability pension (100%) because of back problems	23.3		20.3		17.3	
Working part- or full-time	18.2	1	27.6	1	16.9	3
Litigation or compensation because of back problems	69.4	11	56.5	12	55.6	12
Patient relation of back problems to work injury	59.7	1	54.3	4	48.5	7

* The differences among the groups were calculated using the Mann Whitney *U* test and the χ^2 exact test. There were no significant differences between the groups.

cation. The two major bleedings both occurred during an ALIF procedure, but were managed successfully. Of the 140 patients for whom pedicle screws were used (Groups 2 and 3), 9 (6%) experienced a new sensation of leg pain immediately after surgery. In three patients, a screw penetrating the medial pedicle cortex, as shown on the radiograph, was removed, with immediate relief of symptoms in one patient. Thus eight patients had a new and remaining leg pain of varying intensity and duration after surgery. There were three deep early wound infections (1.4%): one at the donor site and two over the implant. Both healed successfully after debridement. No instruments had to be removed. Two patients in Group 3 had a late infection 6 to 12 months after surgery in connection with the implantation site. In both cases, the instrument was removed, and the fusion areas were found to be healed in one patient. Two patients reported burning pain, a sensation of heat in the lower extremities, and a tendency of swelling after an ALIF procedure. This was attributed to an injury of the sympathetics. Both patients improved over a period of 1 to 2 years, although neither recovered completely. Pain at the donor

Table 2. Pain, Disability, and Depression at Baseline and After 2 Years*

	Group 1 (n = 62) (6 missing) Mean	P*	Group 2 (n = 59) (3 missing) Mean	P*	Group 3 (n = 65) (6 missing) Mean	P*
Back pain						
At baseline	64.1 ± 14.2		63.3 ± 13.3		65.6 ± 15.2	
After 2 years	45.1 ± 23.6	<0.0001	40.4 ± 23.9	<0.0001	45.7 ± 26.7	<0.0001
Leg pain						
At baseline	32.6 ± 23.6		36.1 ± 25.0		36.7 ± 27.8	
After 2 years	25.9 ± 24.8	0.03	29.6 ± 27.5	0.1	31.7 ± 28.2	0.131
Oswestry						
At baseline	47.3 ± 11.3		48.4 ± 11.6		47.3 ± 10.9	
After 2 years	36.5 ± 16.3	<0.0001	33.6 ± 17.9	<0.0001	38.5 ± 18.9	0.0006
Million						
At baseline	63.1 ± 9.9		64.2 ± 11.7		64.5 ± 12.1	
After 2 years	46.2 ± 21.0	<0.0001	44.4 ± 23.8	<0.0001	47.8 ± 23.6	<0.0001
GFS						
At baseline	47.8 ± 16.2		47.5 ± 15.6		52.5 ± 15.4	
After 2 years	35.5 ± 21.7	0.0004	29.9 ± 21.0	<0.0001	36.3 ± 24.3	<0.0001
Zung						
At baseline	38.8 ± 13.4		38.5 ± 12.6		40.4 ± 14.1	
After 2 years	30.0 ± 13.9	0.0001	30.9 ± 15.3	0.0003	33.3 ± 16.4	0.004

* Pain was measured on a vertical visual analog scale, and functional disability with the Oswestry Low Back Pain Questionnaire, the Million Scale, and General Function Score (GFS). Depressive symptoms were measured with the Zung Depression Scale. All scores ranged from 0 to 100 (maximum severity). The group changers (Group 2 = 5, Group 2= 9, Group 3 = 4) and the dropouts (Group 2 = 3) were excluded. There were no significant differences among the groups regarding the changes in each group after 2 years, according to the Kruskal-Wallis test.
† The difference in each group between baseline and 2-year follow-up assessment was calculated with the Wilcoxon sign rank test.

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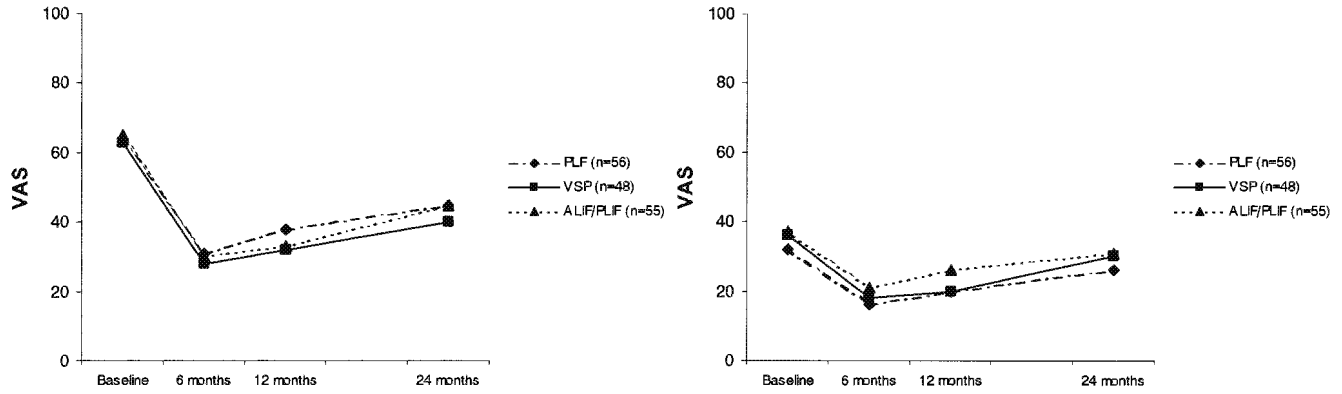

Figure 2. **A,** The χ^2 test was used to calculate *P* values. In all the groups, back pain decreased significantly at all measuring points in time, as compared with the baseline value. There were no significant differences between the groups. Pain increased between 12 and 24 months. Group 1 ($P = 0.028$), Group 2 ($P = 0.018$), Group 3 ($P < 0.0001$). **B,** Leg pain decreased significantly in all the groups and on all measuring points in time, as compared with the baseline value. There were no significant differences between the groups.

site was common, but noted as a problem in only nine patients.

The patient in Group 3 whose operation was performed at the wrong level (L3–L4) underwent reoperation at the right level (L4–L5) after 6 months. The previous fusion was clinically and radiologically healed, and the result was included and reported 2 years after the second operation. Surgery and fusion were repeated for two patients (both in Group 1) in whom pseudarthrosis developed within 1 year, although without any obvious benefit. There were no differences in complication rates between Group 3alif and Group 3plif.

Radiographic Fusion Rate and Number of Fused Levels

The overall fusion rate was 83%: 72% in Group 1, 87% in Group 2, and 91% in Group 3. Instrumented fusions healed more readily than noninstrumented fusions ($P = 0.004$) (Table 6). A total of 668 screws were used in 140 patients. The clinical outcome or complication rate did not correlate with the number of levels addressed, nor did radiographic fusion correlate significantly with clinical outcome. The difference in median disc heights between baseline and 2-year follow-up assessment was small in the interbody group (ALIF/PLIF), indicating that the intention fuse *in situ* was successful in most cases, and that there generally was not a problem with loss of disc height after surgery (Table 7).

Table 3. Patient Overall Rating of the Result at the 2-Year Follow-up Assessment*

	Group 1 (n = 67)	Group 2 (n = 60)	Group 3 (n = 68)
Missing	1	2	3
Much better	22.4	36.7	27.9
Better	37.3	31.7	32.4
Unchanged	28.4	18.3	23.5
Worse	11.9	13.3	16.2
Total	100	100	100

* Values are stated as percentages. Group changers and dropouts were excluded. There were no significant differences among the groups ($P = 0.618$), χ^2).

Work Status

In all the groups, significantly more patients were working after 2 years than at baseline. The net back-to-work rate in each of the three groups was 35% in Group 1, 35% in Group, and 37% in Group 3. These differences were not significant. For this calculation, the number of patients who stopped working was subtracted from the number who returned to work in each study group.

Previous Successful Surgery for a Herniated Disc More Than 2 Years Before Randomization

Surgery for a herniated disc 2 years or more before randomization has been successful in 37 patients: 17 in Group 1, 11 in Group 2, and 9 in Group 3. The number of patients was small in each group, but the results did not differ significantly from those achieved in the three main surgical groups. There was no tendency for a better result in terms of the leg pain component in subgroup 3PLIF (n = 4), in which the nerve root may have been decompressed as a part of the technique. There were no statistically significant differences among the groups in

Table 4. Hospitalization Data and Mean Values*

	Group 1 (n = 68)	Group 2 (n = 60)	Group 3 (n = 70)
Missing	0	2	1
Operation time (minutes)	110 ± 38.0	194 ± 76.8	335 ± 98
Blood loss (mL)	665 ± 895	1284 ± 1125	1433 ± 1236
Blood transfusion (units used)	0.6 ± 1.3	2.7 ± 11.8	2.5 ± 2.4
Days in hospital after surgery	8.5 ± 2.6	9.7 ± 3.2	11.5 ± 3.7

* The group changers (Group 1 = 5, Group 2 = 9, Group 3 = 4) were excluded. According to the Kruskal Wallis test, the differences among the groups were highly significant ($P < 0.0001$). Therefore, with a pairwise comparison was performed using the Mann Whitney *U* test, but because of multiple comparison considerations, a significance value of $P = 0.01$ was required. There was a significant difference between Groups 1 and 2 regarding operative time ($P < 0.0001$) and blood loss ($P < 0.0001$), and a significant difference between Groups 2 and 3 regarding operative time ($P = 0.005$) and days in the hospital ($P = 0.005$). There was a significant difference regarding all variables between Groups 1 and 3 ($P < 0.0001$).

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Table 5. Complications*

	Major	Minor
Group 1 (n = 71)		
Early	1 Thrombosis + pulmonary embolus	1 Superficial wound infection 1 Wingscapula after surgery 1 Gastrointestinal bleeding
Late	2 Pseudarthroses that needed new surgery	1 Donor-site pain
Early complications: 4/71 (5.6%)		
Group 2 (n = 68)		
Early	2 Deep wound infections 1 Nerve root hit by pedicle screw that needed new surgery 1 New sensation of nerve root pain 1 Thrombosis	2 Gastrointestinal bleedings 1 Superficial wound infection 1 Laterally placed screw 1 Pain in the arm after surgery 1 Skin problem after surgery
Late	2 Deep wound infections that needed new surgery	1 Donor-site pain
Early complications: 11/68 (16.2%)		
Group 3 (n = 72)		
Early	5 New sensations of nerve root pain 2 Nerve roots hit by pedicle screw that needed new surgery 2 Major bleedings during surgery 1 Aspiration-sepsis-ARDS 1 Pulmonary edema 1 Heart failure + gastrointestinal bleeding 1 Deep wound infection 1 Patient with surgery on the wrong level	2 Sympathetic chain damages 2 Hematomas at the donor site 1 Dural tear 1 Skin problem on the chin 1 Damage of the nervus cut fem lat at the donor site 1 Laterally placed screw
Late		7 Donor-site pain
Early complications: 22/72 (30.6%)		

* Group changers (Group 1 = 5, Group 2 = 9, Group 3 = 4) from the surgical to the nonsurgical group were excluded, and group changers in the opposite direction (Group 1 = 3, Group 2 = 3, Group 3 = 1) were included, leaving 211 patients for the analysis. Complications were divided into early and late, major and minor. "Early" refers to the first 2 weeks. According to the χ^2 test, there was a significant difference among the groups ($P = 0.0004$). Therefore, as test in pairs was performed, but an exact P value of 0.01 was required. There was no significant difference regarding early complications between Groups 1 and 2 ($P = 0.057$) or between Groups 2 and 3 ($P = 0.049$). There was a significant difference between Groups 1 and 3 ($P = 0.0001$).
ARDS = acute respiratory distress syndrome.

terms of the outcome as assessed by the patient and the independent observer.

Circumferential Fusion Subdivided Into ALIF and PLIF

In Group 3, 56 patients underwent an ALIF procedure, and 19 patients underwent a PLIF procedure. There were no differences in sociodemographic and clinical characteristics between the subgroups, and the outcome did not differ in terms of pain, disability, depressive symptoms, overall rating of the result by the patient or the independent observer, complications, or fusion rate.

Discussion

All surgical techniques used in the study could reduce pain and decrease disability among selected patients with severe CLBP, but there were no discernible differences among the procedures regarding the outcome as measured by pain, disability, rating by the patient or independent observer, or number of patients working. To minimize difficulties in interpreting the results, a relatively homogeneous patient group was used, which also was compared with an age- and gender-matched sample

Table 6. The Proportion of Radiographically Fused Levels After 2 Years*

	Group 1 (n = 67)			Group 2 (n = 62)			Group 3 (n = 64)			
	All % (n)	1 Level % (n)	2 Levels % (n)	All % (n)	1 Level % (n)	2 Levels % (n)	All % (n)	1 Level % (n)	2 Levels % (n)	Patients (n)
Definitely fused	72 (48)	78 (28)	65 (20)	87 (54)	94 (33)	78 (21)	91 (58)	91 (39)	91 (19)	162
Doubtful/pseudarthrosis	28 (19)	22 (8)	35 (11)	13 (8)	6 (2)	22 (6)	9 (6)	9 (4)	9 (2)	35
Total	100 (67)	100 (36)	100 (31)	100 (62)	100 (35)	100 (27)	100 (64)	100 (43)	100 (21)	197

* Group changers and dropouts (n = 25) were excluded. P values were calculated with χ^2 test. The fusion site was considered to be healed in Groups 1 and 2 if both posterolateral areas were solid on plain radiograph. In Group 3, the fusion was considered to be sufficient if the interbody site had a solid appearance. There were no significant differences in the fusion rates between one and two levels in any group: Group 1 ($P = 0.282$), Group 2 ($P = 0.069$), and Group 3 ($P = 1.0$). Based on all patients, the fusion rate was not significantly better if one level (88%) or two levels (79%) were fused ($P = 0.051$). The radiologhically assessed fusion rate was significantly better when internal fixation was used (Group 2 + Group 3), as compared with the noninstrumented group (Group 1) ($P = 0.004$).

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Table 7. Disc Height Changes 2 Years After ALIF/PLIF*

	Median	IQR
L4–L5 (n = 14)	0.8	(−0.9–5.6)
L5–S1 (n = 24)	1	(−0.5–4.4)
L4–S1 (n = 17)	2	(0–3.5)

* Median values in millimeters and interquartile range (IQR). The analysis included 55/71 patients (77%). In the L4–S1 subgroup, the combined change from L4–L5 and L5–S1 is presented.
ALIF = anterior lumbar interbody fusion; PLIF = posterior lumbar interbody fusion.

of the general population.[28] Patients with recognized diagnoses such as isthmic spondylolisthesis (instrumented *vs* noninstrumented fusion of these patients was described in a recent randomized study[43]) and those with pain after failed back surgery were deliberately excluded because patients with different diagnoses could report different patterns of both pain and disability, and also could respond differently to treatment.

The patients in the current study were defined through precise inclusion and exclusion criteria regarding history, clinical appearance, radiographic changes, and duration of pain and disability. This, together with the relatively large number of patients in each group, should have made it possible to detect any major statistically valid differences in outcome among the groups.

In an attempt to make possible comparisons with other reports, well-known instruments and methods were used to measure outcome: a visual analog scale for pain, the Oswestry Low Back Pain Questionnaire for disability, and a global self-rating scale. However, it is difficult to make valid comparisons using results derived from different periods, socioeconomic cultures, and patient populations. Valid comparisons are even more difficult if different diagnostic groups are involved. Hopefully, the increasing use of quality of life scales, which permit measurement of patient-reported utility, will make these interstudy comparisons more relevant. When the current Oswestry scores were compared with those of Kozak and O'Brien,[38] who between 1984 and 1986 performed a 360 fusion in 27 patients (mean age, 40 years) with CLBP, we found similar scores before treatment start, 47.3% and 47.4% respectively, but a comparably big difference (38.5% and 26.6%) after approximately two years. It is not obvious what useful conclusions can be drawn from this comparison except that both patient groups were very disabled before surgery, and that surgery could improve the status but could not cure the patient.

This study did not have the power to detect small differences as significant. To have 80% power and a 5% significance level, there would need to be a 17% unit difference between the groups for any outcome result measured. Only a 0.6% unit (work) to 8% unit (self-rating) difference was detected depending on the outcome variable used. This indicates that if the differences found were real, there should be a need for 500 to several thousand patients in each treatment sector to prove a difference as significant. It is possible that such differences are not clinically relevant. Of course, it is also possible that new surgical techniques and a better patient selection could increase the differences between the procedures, but this remains to be demonstrated.

The hypothesis behind fusion surgery for CLBP is that a degenerated and mobile lumbar segment acts as a pain generator. Consequently, if motion is prohibited through a fusion, it is expected that the patient will experience improvement in both pain and disability. Currently, there is no way to be certain which structure or structures actually are causing the pain, but the main interest has been focused on the facet joints, the disc, and a combination of the two. Different surgical techniques have been advocated depending on this. The current study did not differentiate between possible pain-generating structures because controversy remains regarding the prognostic value of such an undertaking,[14,45,46] but the authors postulated that it would be possible to reduce pain and decrease disability through the stabilizing effect of a fusion, regardless of the origin. Consequently, patients were included in the study who had been labeled as experiencing low back pain of unknown origin, discogenic pain,[9] facet syndrome,[44] segmental pain,[21] and degenerative disc disease.[42]

The overall result from fusion surgery in this prospective study (retrospective studies have been shown to report better results[58]) assessed by patients as "much better" or "better" was between 60% (Group 1) and 68% (Group 2). The authors join others in the opinion that restoring a patient with CLBP to normalcy is beyond the expectation of surgical fusion, regardless of technique used. The goal instead is to improve the patients' symptoms sufficiently to make an important subjective, and hopefully also objective (measurable), difference, as compared with the effects of natural history, placebo, or other nonsurgical treatment options. Surgical fusion has been demonstrated to have this potential, as the Swedish Lumbar Spine Study Group shows in a previous report.[20] There is, however, a need to compare surgical fusion over the long term with different nonsurgical treatments that have produced better results than natural history or placebo, at least in a short perspective.[59]

If fusion is considered as treatment for CLBP, the surgeon should strive to use the most adequate technique possible for each individual patient. This technique should involve the least technically demanding procedure because the risk of complications and the cost rise with increasing technicality. Therefore, if a more technically demanding procedure is considered, the possible advantages must be clear to the patient, the surgeon, and those who are responsible for the allocation of funds and resources.

The findings from this study show that the clinical outcome after the relatively simple posterolateral fusion, technically speaking, was not inferior to the outcome from more advanced techniques. The important compo-

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nent seemed to be the immobilization of the motion segment or segments, whereas the technique used to accomplish this was of lesser importance.

A correlation was found between the back pain and the leg pain components. The percentage of the nonspecific leg pain component was reduced in all the groups by approximately half of the back pain component. Findings show that the leg component likely is referred pain from the back, and that both improve through the stabilizing effect of the fusion procedure.

In this study, the increase in back pain 1 to 2 years after surgery was unsuspected because others, such as Moller and Hedlund,[43] have reported no further increase in pain after 1 year. This finding demonstrates the necessity of further follow-up evaluation.

The reported fusion rate in this study using standard radiograph was relatively high, but comparable with that of others. However, this estimation is difficult with the use of plain radiographs, especially in the presence of metal implants, which obscure vision. Consequently, the fusion rate can be either underestimated or overestimated.[3,6,35] An examination protocol was distributed to all the participating centers in an attempt to secure radiographic exposures that were as similar as possible. Because no bone markers were inserted during the operation, measurements were negatively affected by the usual approximations associated with the use of ordinary radiographs. A disturbing finding, which the authors share with others, is that there was no correlation between an osseous fusion and a positive patient rating of the result in any group.[17,23,43,57] This estimation may reflect a "true finding," but it may possibly be the result of low accuracy from plain radiographs used to detect definite fusion.[3]

In this study, the addition of an internal fixation device significantly increased the fusion rate, both when the three groups were compared ($P = 0.009$) and when the instrumented groups (Group 2 and Group 3) were added and compared with the noninstrumented group ($P = 0.004$). This finding agrees with the result reported by Fischgrund et al[17] from a randomized study in which instrumented fusion and noninstrumented fusion for degenerative lumbar spondylolisthesis were compared, but contrasts with that of several other randomized studies.[18,43,57] In a Cochrane review, Gibson et al[23] reported that there seems to be valid scientific evidence for a positive correlation between fusion and the use of internal fixation. However, it is difficult to estimate fusion on a plain radiograph. This becomes even more difficult when metal is present (as in Groups 2 and 3). The comparison is therefore somewhat uncertain, which should be remembered in the interpretation of these findings. Another possible advantage of an internal fixation, to which spine surgeons often refer, is that the patient may be more easily mobilized and rehabilitated after surgery. Although this may very well be true, it was not tested in this study, and the possible advantage must be weighed against a higher risk of both early and late complications if a fixation device is used.

All the procedures in the current study included a posterior approach, in which muscle tissue must be mobilized and thereby damaged, which probably can cause pain. Greenough et al[26] compared a study on ALIF with a following consecutive study on posterolateral fusion. They concluded that the results after posterior instrumented fusion are poor, possibly because of damaged muscle tissue acting as a pain generator, and proposed on the basis of evidence, that anterior fusion might provide better results, at least according to disability, but not according to self-reported satisfaction rating. The current authors believe that a randomized comparison of ALIF with posterior fusion in a homogeneous patient population is needed to verify that statement.

There were 14 major early complications (nine in Group 3). For the most part, they were managed with no obvious sequelae for the patient. Nine patients experienced a new sensation of leg pain after surgery, all of them in the groups wherein pedicle screws had been used (6%). In most of these patients, there was no obvious penetration of the pedicle cortex by a screw, which might have explained the sensation. However, at least for patients in whom the spinal canal was not exposed (as in Group 2 and Group 3alif), a screw must be suspected as causing the pain. The pain also persisted in eight patients. This potentially new pain inflicted on the patients certainly is a disadvantage with the use of pedicle screws. Pain over the donor site was noted as a problem in only nine patients, but it probably is more common. Harvesting autogenous bone during lumbar fusion adds to the risk of postoperative morbidity.

Group 3 was subdivided into Group 3ALIF and Group 3PLIF. Because Group 3PLIF had relatively few patients (n = 19), it is difficult to draw any valid conclusions about the comparison. For example, back and leg pain, as well as the measurements used to reflect disability, improved numerically in the same magnitude as in Group 3ALIF, but because of the relatively few patients, the statistical outcome was not as good. Hypothetically, in addition to achieving a fusion, the PLIF technique, as a part of the procedure, also could decompress neural structures because it involves entering the spinal canal. However, no tendency toward a better outcome with reference to the leg pain component could be seen in the PLIF group. Also, leg pain was improved at least as much in Group 1 as in the other groups after 2 years.

Because the study was multicentered, some surgeons performed more procedures in the study than others. The authors do not believe, however, that there was an important difference in skill between participating surgeons because they all routinely performed spine surgery. There also was no difference in clinical or technical outcome (*i.e.*, complications and fusion rate) between participating centers. The study protocol did not permit differentiation among the surgeons. When an analysis of the first 100 patients who underwent surgery between

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1992 and 1994 was performed and compared with that of the last 100 who underwent surgery between 1995 and 1998, there also was no difference in outcome.

In Sweden, fusion surgery for patients with severe CLBP of nonspecific origin in whom nonsurgical therapies have failed constitutes approximately 5% of the spine surgery schedule. Thus, of the approximately 6300 spine procedures (70 per 100,000 residents) performed in 1999,[52] only a few more than 300 arthrodeses were performed in patients with CLBP of unknown etiology. Some of these approximately 300 patients met the inclusion criteria for the current study. Because much of the discussion about spine surgery in its entirety revolves around the question of fusion surgery in this comparably small patient category, at least in Sweden, this relation is worth remembering.

Conclusion

In this randomized study conducted on a selected and comparably homogeneous group of patients with severe and therapy-resistant CLBP, all three surgical techniques used were shown to reduce pain and decrease disability significantly. In this selected patient population, there was no obvious disadvantage in using the technically least demanding posterolateral fusion procedure, without internal fixation or additional interbody fusion (Table 1).

Key Points

- A multicenter prospective randomized clinical study was conducted.
- For this study, 201 patients with severe chronic low back pain were randomized to three different surgical treatment groups.
- All the surgical techniques used could significantly reduce pain and decrease disability.
- There were no significant differences between the techniques.

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Randomized Trial

Circumferential Lumbar Spinal Fusion With Brantigan Cage *Versus* Posterolateral Fusion With Titanium Cotrel–Dubousset Instrumentation

A Prospective, Randomized Clinical Study of 146 Patients

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- Buy

Abstract

Study Design.

A prospective randomized clinical study with a 2-year follow-up period was conducted.

Objective.

To analyze the effects of circumferential fusion using ALIF radiolucent carbon fiber cages and titanium posterior instrumentation on functional outcome, fusion rate, complications, and lumbar lordosis.

Summary of Background Data.

Circumferential fusion has become a common procedure in lumbar spine fusion, both as a primary and salvage procedure. However, the claimed advantages of ALIF plus PLF over conventional PLF lack scientific documentation.

Methods.

From April 1996 through November 1999, a total of 148 patients with severe chronic low back pain were randomly selected for either posterolateral lumbar fusion with titanium CD-Horizon (posterolateral group) or circumferential fusion with a ALIF Brantigan cage plus posterior instrumentation. The Dallas Pain Questionnaire (DPQ), the Low Back Pain Rating Scale (LBPR), and a questionnaire concerning work status assessed their outcomes.

Results.

Both groups showed highly significant improvement in all four categories of life quality (DPQ) as well as in the back pain and leg pain index (LBPR), as compared with preoperative status. There was a clear tendency toward better overall functional outcome for patients with the circumferential procedure ($P < 0.08$), and this patient group also showed significantly less leg pain at the 1-year follow-up evaluation ($P < 0.03$) and less peak back pain at 2 years ($P < 0.04$). Sagittal lordosis was restored and maintained in the circumferential group ($P < 0.01$). The circumferential fusion patients showed a higher posterolateral fusion rate (92%) than the posterolateral group (80%)($P < 0.04$). The repeat

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operation rate including implant removal was significantly lower in the circumferential group (7%) ($P < 0.009$) than in the posterolateral group (22%).

Conclusions.

Circumferential lumbar fusion restored lordosis, provided a higher union rate with significantly fewer repeat operations, showed a tendency toward better functional outcome, and resulted in less peak back pain and leg pain than instrumented posterolateral fusion. The clinical perspective of the current study implies a recommendation to favor circumferential fusion as a definitive surgical procedure in complex lumbar pathology involving major instability, flatback, and previous disc surgery in younger patients, as compared with posterolateral fusion with pedicle screws alone.

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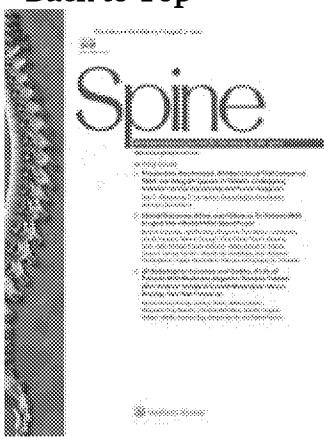

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Meta-Analysis in Clinical Trials*

Rebecca DerSimonian and Nan Laird

ABSTRACT: This paper examines eight published reviews each reporting results from several related trials. Each review pools the results from the relevant trials in order to evaluate the efficacy of a certain treatment for a specified medical condition. These reviews lack consistent assessment of homogeneity of treatment effect before pooling. We discuss a random effects approach to combining evidence from a series of experiments comparing two treatments. This approach incorporates the heterogeneity of effects in the analysis of the overall treatment efficacy. The model can be extended to include relevant covariates which would reduce the heterogeneity and allow for more specific therapeutic recommendations. We suggest a simple noniterative procedure for characterizing the distribution of treatment effects in a series of studies.

KEY WORDS: *random effects model, heterogeneity of treatment effects, distribution of treatment effects, covariate information*

INTRODUCTION

Meta-analysis is defined here as the statistical analysis of a collection of analytic results for the purpose of integrating the findings. Such analyses are becoming increasingly popular in medical research where information on efficacy of a treatment is available from a number of clinical studies with similar treatment protocols. If considered separately, any one study may be either too small or too limited in scope to come to unequivocable or generalizable conclusions about the effect of treatment. Combining the findings across such studies represents an attractive alternative to strengthen the evidence about the treatment efficacy.

The main difficulty in integrating the results from various studies stems from the sometimes diverse nature of the studies, both in terms of design and methods employed. Some are carefully controlled randomized experi-

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ments while others are less well controlled. Because of differing sample sizes and patient populations, each study has a different level of sampling error as well. Thus one problem in combining studies for integrative purposes is the assignment of weights that reflect the relative "value" of the information provided in a study. A more difficult issue in combining evidence is that one may be using incommensurable studies to answer the same question. Armitage [1] emphasizes the need for careful consideration of methods in drawing inferences from heterogeneous but logically related studies. In this setting, the use of a regression analysis to characterize differences in study outcomes may be more appropriate [2].

This paper discusses an approach to meta-analysis which addresses these two problems. In this approach, we assume that there is a distribution of treatment effects and utilize the observed effects from individual studies to estimate this distribution. The approach allows for treatment effects to vary across studies and provides an objective method for weighting that can be made progressively more general by incorporating study characteristics into the analysis. We illustrate the use of this model in several examples, and based on the empirical evidence, suggest a simple noniterative procedure for testing and estimation.

DATABASE

In a systematic search of the first ten issues published in 1982 of each of four weekly journals (*NEJM*, *JAMA*, *BMJ*, and *Lancet*), Halvorsen [3] found only one article (out of 589) that considered combining results using formal statistical methods. Our data consist of an ad hoc collection of such articles from the medical literature found through references provided by colleagues and through bibliographic references in articles already located [4–11]. The method we propose applies to several additional articles that have come to our attention since our original analyses [12–14].

We examine in detail eight review articles each reporting results from several related trials. Each review pools the results from the relevant trials in order to evaluate the efficacy of a certain treatment for a specified medical condition. In most of these reviews the original investigators pool the results from the relevant trials and estimate an overall treatment effect without first checking whether the treatment effect across the trials is constant. Others exclude some trials and combine the results only from trials that are similar in design and implementation. The investigators who do check for homogeneity of treatment effect before pooling use different criteria to assess this homogeneity. With two exceptions [6,11], the reviews consider randomized trials only. The two reviews that include nonrandomized studies analyze the data from the two groups of studies (randomized and nonrandomized) separately. In this study, we restrict our attention to the results of randomized trials only. We first describe the eight reviews identifying each by its first author, and in Table 1 summarize the methods used in each review:

Winship: A review of eight trials that compare the healing rates in duodenal ulcer patients treated with cimetidine or placebo therapy [4].

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Table 1 The Methods and Outcome Measures Used in the Original Reviews

	Outcome measure	Overall effect estimate	Test of homogeneity
Winship	difference in proportions	pooled raw data	———
Conn	difference in proportions	pooled raw data	———
Miao	difference in proportions	weighted average	Chi-Square Test (Q_w)
DeSilva	relative risk	Mantel–Haenszel estimate for pooled relative risk	———
Stjernsward	difference in proportions	minimum and maximum	———
Baum	difference in proportions	pooled raw data	Gilbert, McPeek, and Mosteller estimate of variance [15]
Peto	difference in proportions	———	Mentions lack of heterogeneity
Chalmers	difference in proportions	unweighted average	———

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Conn: A review of nine trials that compare the survival rates in alcoholic hepatitis patients with steroids or control therapy [5].

Miao: A review of six trials that compare gastric with sham freezing in the treatment of duodenal ulcer [6]. In addition, this review considers 14 observational and two controlled but nonrandomized studies.

DeSilva: A review of six trials that evaluate the effect of lignocaine on the incidence of ventricular fibrillation in acute myocardial infarction [7]. This study originally considered 15 trials but because the trials vary widely in treatment schedules and doses, some criteria for adequacy of treatment are established and only six trials that fulfill these requirements are analyzed.

Stjernsward: A review of five trials that compare the 5-year survival rates of patients with cancer of the breast treated with surgery plus radiotherapy or surgery alone [8].

Baum: A review of 26 trials that evaluate the efficacy of antibiotics in the prevention of wound infection following colon surgery [9].

Peto: A review of six trials that evaluate the efficacy of aspirin in the prevention of secondary mortality in persons recovered from myocardial infarction [10].

Chalmers: A review of a number of trials that evaluate the efficacy of anticoagulants in the treatment of acute myocardial infarction [11]. Data from 18 surveys employing historical controls (HCT), eight studies employing alternately assigned controls (ACT), and six randomized controlled trials (RCT) are given. Three endpoints, total case fatality rates, case fatality rates excluding early deaths, and thromboembolism rates are considered, although not all studies report all three endpoints. Here we consider thromboembolism and total case fatality rates in the RCTs only. The results from randomized trials are compared to those of nonrandomized ones (HCTs and ACTs) in Laird and DerSimonian [16].

METHODS

We consider the problem of combining information from a series of k comparative clinical trials, where the data from each trial consist of the number of patients in treatment and control groups, n_T and n_C, and the proportion of patients with some event in each of the groups, r_T and r_C. Letting i index the trials, we assume that the numbers of patients with the event in each of the study groups are independent binomial random variables with associated probabilities p_{Ti} and p_{Ci}, $i = 1, \ldots, k$. The basic idea of the random effects approach is to parcel out some measure of the observed treatment effect in each study, say y_i, into two additive components: the true treatment effect, θ_i, and the sampling error, e_i. The variance of e_i is the sample variance, s_i^2, and is usually calculated from the data of the ith observed sample. The true treatment effect associated with each trial will be influenced by several factors, including patient characteristics as well as design and execution of the study. To explicitly account for the variation in the true effects, the model assumes

$$\theta_i = \mu + \delta_i$$

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where θ_i is the true treatment effect in the ith study, μ is the mean effect for a population of possible treatment evaluations, and δ_i is the deviation of the ith study's effect from the population mean. We regard the trials considered as a sample from this population and use the observed effects to estimate μ as well as the population variance [$\text{var}(\delta) = \Delta^2$]. Here, Δ^2 represents both the degree to which treatment effects vary across experiments as well as the degree to which individual studies give biased assessments of treatment effects.

The model just described can thus be characterized by two distinct sampling stages. First we sample a study from a population of possible studies with mean treatment effect μ and variance in treatment effects of Δ^2. Then we sample observations in the ith study with underlying treatment effect θ_i.

One issue which deserves some attention is the specification of treatment effect, θ_i. Three commonly used measures are the risk difference, $p_{Ti} - p_{Ci}$, the relative risk, p_{Ti}/p_{Ci}, and the relative odds, $[p_{Ti}/(1 - p_{Ti})/p_{Ci}/(1 - p_{Ci})]$. The relative odds is popular because of its suitability in retrospective or case control studies, and because it has some interesting mathematical properties. In particular, if we assume a constant relative odds ($\theta_i = \mu$ or $\Delta^2 = 0$), then the Mantel–Haenszel statistic is optimal for testing H_0: $\mu = 1$, and there is considerable literature on efficient estimates of μ and on methods for testing H_0: $\theta_1 = \theta_2 = \ldots = \theta_k$. Despite these advantages, the relative odds (and the closely related relative risk) suffers in interpretability. By far the most intuitively appealing measure for trials of clinical efficacy is the risk difference, since it measures actual gains which can be expected in terms of percentages of patients treated. Besides relevance of the measure and statistical efficiency, it is also desirable to choose a measure which is nearly constant over studies, so that the effect of heterogeneity is minimized. Unless there is no treatment effect at all ($p_{Ti} = p_{Ci}$ for all i), constancy of treatment effect in one scale (say $p_{Ti}/p_{Ci} = A$ for all i) implies variation across studies in another ($p_{Ti} - p_{Ci}$, say). Thus it is conceivable that the wrong choice of scale could imply heterogeneity in treatment effects which would not exist if a different measure were used. However, this is not likely to happen in practice unless there is a very wide range in the control rates (p_{Ci}) or all the rates are very close to zero (or one). In such cases, one might want to do the analysis in both the relative odds and risk difference scales.

HOMOGENEITY OF TREATMENT EFFECT

To evaluate constancy of treatment effect across strata, we use a large sample test based on the statistic $Q = \sum_i w_i(y_i - \bar{y}_w)^2$, where y_i is the ith treatment effect estimate, $\bar{y}_w = \sum_i w_i y_i / \sum_i w_i$ is the weighted estimator of treatment effect, and w_i is the inverse of the ith sampling variance. The test statistic Q is the sum of squares of the treatment effect about the mean where the ith square is weighted by the reciprocal of the estimated variance. Under the null hypothesis, Q is approximately a χ^2 statistic with $k - 1$ degrees of freedom; thus, when each study has a large sample size relative to the number of strata, Q may be used to test H_0: $\Delta^2 = 0$.

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When y_i is a difference in proportions, $r_{Ti} - r_{Ci}$, we estimate the sampling variance in the ith study, s_i^2, by

$$s_i^2 = r_{Ti}(1 - r_{Ti})/n_{Ti} + r_{Ci}(1 - r_{Ci})/n_{Ci}, \tag{1}$$

and use $Q_w = \sum_i w_i(y_i - \bar{y}_w)^2$ to test constancy of treatment effect.

The weights in Q may vary according to the assumptions made about the sampling variances. For instance, when the sampling variances can be assumed to be equal, then w_i, $i = 1, \ldots, k$, is the inverse of a common sampling variance s^2. One review [9], which includes a qualitative assessment of homogeneity of treatment effect, uses the method of Gilbert et al. [15] to estimate the magnitude of the variation across the differences in proportions. Since the method of Gilbert et al. for estimating the variation in treatment effects assumes a common sampling variance, we calculate Q_u, the analogue of Q_w, assuming equal sampling variances. Here, the treatment effect is again the difference in proportions, but

$$w_i = s^{-2}, \qquad i = 1, \ldots, k,$$

where

$$s^2 = \sum_i s_i^2/k,$$

and s_i^2 is defined in equation (1).

We also use the Q statistic for testing homogeneity in the relative odds scale. In this scale,

$$Q_L = \sum_i w_i (y_i - \bar{y}_w)^2$$

where

$$y_i = \ln [r_{Ti}(1 - r_{Ci}) / r_{Ci}(1 - r_{Ti})],$$

$$w_i = s_i^{-2}, \qquad \bar{y}_w = \sum_i w_i y_i / \sum_i w_i,$$

and

$$s_i^2 = [n_{Ti} r_{Ti}(1 - r_{Ti})]^{-1} + [n_{Ci} r_{Ci}(1 - r_{Ci})]^{-1}.$$

In the large sample case, Q_L is analogous to the goodness-of-fit test in logistic models [17]. An alternate test statistic for assessing homogeneity is the likelihood ratio test which is computationally more cumbersome than the Q statistic used here [18].

ESTIMATION AND COMPUTATION

Most of the reviews consider the differences in proportions as a measure of treatment effect (Table 1). For estimating μ and Δ^2 we also restrict our attention to this scale.

When $\Delta^2 \neq 0$, Q_w is used to derive a noniterative estimate of Δ^2 by equating the sample statistic with the corresponding expected value. This yields a weighted estimator

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$$\Delta_w^2 = \max\{0, \{Q_w - (k-1)\} / [\sum_i w_i - (\sum_i w_i^2 / \sum_i w_i)]\},$$

where Q_w, $\bar{y}_w$, w_i are as described above. The weighted least squares or Cochran's [19] semiweighted estimator of μ is

$$\mu_w = \sum_i w_i^* y_i / \sum_i w_i^*, \tag{2}$$

where

$$w_i^* = (w_i^{-1} + \Delta_w^2)^{-1}. \tag{3}$$

The asymptotic standard error of μ_w is

$$\text{s.e.}\ (\mu_w) = (\sum_i w_i^*)^{-1/2}. \tag{4}$$

When the sampling variances are assumed to be equal, these equations reduce to:

$$\Delta_u^2 = \max[0, \{\sum_i (y_i - \bar{y})^2 / (k-1)\} - s^2],$$

$$\mu_u = \bar{y},$$

and

$$\text{s.e.}\ (\mu_u) = [(s^2 + \Delta_u^2) / k]^{1/2},$$

where

$$\bar{y} = \sum_i y_i / k \quad \text{and} \quad s^2 = \sum_i s_i^2 / k.$$

Rao et al. [20] derive Δ_u^2 from an unweighted sum of squares procedure and show that it is also the Minque estimator when the sampling variances are all equal. The unweighted mean, μ_u, is equivalent to the estimate of the treatment effect in reviews that use the average difference in proportions to assess the overall treatment efficacy.

With an additional assumption that y_i is $N(\theta_i, s_i^2)$ and θ_i is $N(\mu, \Delta^2)$, we also compute maximum likelihood (ML) and restricted maximum likelihood (REML) estimates and compare them to the noniterative ones. The maximum likelihood estimates of the unknown parameters are those values that maximize the probability density function of the data. In REML estimation, the likelihood to be maximized is slightly modified to adjust for μ and Δ^2 being estimated from the same data. The REML estimators are the iterative equivalents of the weighted estimators above. Both ML and REML estimates of μ and its s.e. take the form given in equations (2) and (4) with weights given in (3), but differ in the way Δ^2 is estimated.

The ML estimating equations are given in Rao et al. [20] and the REML equations are reviewed by Harville [21]. For implementing the ML or REML procedures, we use the EM algorithm [22] which is an iterative procedure for computing maximum likelihood estimates appropriate when the observations can be viewed as incomplete data.

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RESULTS

Homogeneity of Treatment Effect

We present the statistics for testing homogeneity of treatment effect in Table 2. For these reviews Q_w, the weighted statistic in the difference scale, and Q_L, the analogous statistic in the log odds scale, imply similar conclusions about the constancy of treatment effect. The assumption of homogeneity holds in the reviews by DeSilva [7], Stjernsward [8], Peto [10], and in Chalmers' [11] randomized controlled trials (case fatality rates). In the remaining five sets of trials, the evidence suggests heterogeneity of treatment effect irrespective of the scale of measurement.

The review by Peto [10] mentions lack of heterogeneity in treatment effects across trials. For this review, the Q_u statistic supports the homogeneity assumption (p value = 0.65), whereas both Q_w and Q_L support that assumption only marginally (p value = 0.12). Baum et al. [9] estimate the variability in treatment differences using the method of Gilbert et al. [15] and conclude that relative to within study variation (assumed equal for all studies), between study variation is negligible. This qualitative assessment is not consistent with the results of Table 2 where a common treatment effect across the trials in this review does not seem to hold in either scale of measurement. The third review which includes a test of homogeneity before pooling the results [6] uses a slightly modified version of Q_w to test this hypothesis and the conclusion of lack of homogeneity agrees with the result in Table 2.

As in the review by Peto [10], Q_u and Q_w imply different conclusions about the homogeneity of treatment effect in the review by Winship [4]. In this review also, the method assuming equal weights (Q_u) implies homogeneity of effect while the weighted one implies the opposite.

These results emphasize that the variation in the treatment effect across several trials is often not negligible and should be incorporated into the anal-

Table 2 Test of Homogeneity[a]

	df[c]	Q_w[d]	Q_L[e]	Q_u[f]
Winship	7	15.2[b]	15.6[b]	7.9
Conn	8	15.6[b]	20.6[b]	19.3[b]
Miao	5	21.7[b]	18.8[b]	20.9[b]
DeSilva	5	9.1	4.4	7.3
Stjernsward	4	2.1	2.2	2.7
Baum	25	40.4[b]	35.2[b]	35.3[b]
Peto	5	9.0	9.2	3.5
Chalmers				
Thromboembolism	5	12.3[b]	10.3[b]	10.6[b]
Case fatality rates	5	3.5	2.4	1.8

[a]Figures in Tables 2–4 are based on data available at the time of review publication.

[b]p value <0.10.

[c]Degrees of freedom.

[d]Q statistic in difference scale (unequal weights).

[e]Q statistic in log odds scale (unequal weights).

[f]Q statistic in difference scale (equal weights).

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ysis of the overall treatment efficacy. Lack of homogeneity holds both when the treatment effect is the difference in proportions and when it is the log odds. The unweighted statistic which assigns an equal weight to each study may not be appropriate for testing homogeneity when differences in sample sizes and/or underlying proportions across studies are large.

Estimation

For all four methods of estimation we present estimates of μ and its s.e. in Table 3, and estimates of Δ^2 in Table 4. The estimates of Δ^2, and s.e. ($\hat{\mu}$) are quite similar in the weighted noniterative method, maximum likelihood, and restricted maximum likelihood procedures. The Δ^2s from these three methods are zero or nearly so in the reviews by DeSilva [7], Stjernsward [8], Peto [10], and Chalmers' [11] randomized trials (case fatality rates). These same reviews have Q statistics that are small relative to their degrees of freedom (Table 2). The weighted method and the REML estimation procedures consistently yield slightly higher values of Δ^2 than the ML procedure. This is because both these procedures adjust for μ and Δ^2 being estimated from the same data whereas the ML procedure does not. The estimates of μ and its s.e. from these three procedures are expected to be similar since the estimates of Δ^2 are almost equal.

Comparing the unweighted method of moments with the other three methods, we find that the estimates for Δ^2 from this method differ, and sometimes differ widely, from the estimates of the other three methods but without any consistent pattern. The estimates of μ and its s.e. from the unweighted method also differ from the estimates of the other three methods and these differences are not necessarily due to the differences in Δ^2s. In Chalmers' [11] randomized trials (case fatality rates), for instance, even when Δ^2 is zero for all four methods, the estimate of μ is 0.042 (s.e. = 0.024) for the unweighted method while it is 0.029 (s.e. = 0.012) for the other three methods. The original reviewers report the unweighted average of the observed rate differences

Table 3 Estimated Overall Effects and Their Standard Errors[a]

	μ_u[b]	μ_w[c]	μ_M[d]	μ_R[e]
Winship	0.406 (0.046)	0.389 (0.058)	0.384 (0.053)	0.387 (0.056)
Conn	0.102 (0.092)	0.075 (0.072)	0.070 (0.063)	0.073 (0.069)
Miao	0.077 (0.125)	0.094 (0.111)	0.095 (0.106)	0.093 (0.118)
DeSilva	0.026 (0.019)	0.027 (0.019)	0.026 (0.017)	0.027 (0.019)
Stjernsward	0.046 (0.020)	0.041 (0.018)	0.041 (0.018)	0.041 (0.018)
Baum	0.203 (0.031)	0.208 (0.026)	0.208 (0.025)	0.208 (0.026)
Peto	0.018 (0.008)	0.015 (0.008)	0.014 (0.008)	0.015 (0.008)
Chalmers				
Thromboembolism	0.102 (0.036)	0.079 (0.020)	0.078 (0.017)	0.078 (0.020)
Case fatality rates	0.042 (0.024)	0.029 (0.012)	0.029 (0.012)	0.029 (0.012)

[a]Figures in parentheses represent the standard errors of the corresponding estimates.

[b]Noniterative estimates with equal weights.

[c]Noniterative estimates with weights to reflect unequal variances.

[d]Maximum likelihood estimates.

[e]Restricted maximum likelihood estimates.

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Table 4 Estimated Variation in the True Effects

	Δ_u^{2a}	Δ_w^{2b}	Δ_M^{2c}	Δ_R^{2d}
Winship	0.0020	0.0137	0.0096	0.0117
Conn	0.0442	0.0208	0.0112	0.0176
Miao	0.0716	0.0540	0.0482	0.0638
DeSilva	0.0007	0.0009	0.0006	0.0009
Stjernsward	0	0	0	0
Baum	0.0072	0.0062	0.0049	0.0057
Peto	0	0.0002	0.0002	0.0002
Chalmers				
Thromboembolism	0.0041	0.0012	0.0007	0.0012
Case fatality rates	0	0	0	0

[a]Noniterative estimates with equal weights.

[b]Noniterative estimates with weights to reflect unequal variances.

[c]Maximum likelihood estimates.

[d]Restricted maximum likelihood estimates.

(0.042) as an estimate of overall treatment efficacy. The weighted estimate of the treatment effect which weights the observed effects in relation to sample size is lower than the unweighted average, since some of the larger studies have smaller estimated treatment effects.

DISCUSSION

We have used a simple random effects model for combining evidence, and applied it to characterize the distribution of treatment effects in a series of studies. The model is useful both in summarizing the data and in illustrating the different kinds of results which one obtains from randomized and nonrandomized studies. In general, studies with greater potential for bias, such as uncontrolled or nonrandomized ones, show greater treatment effect as well as greater heterogeneity [2,16].

One important finding that emerges from this investigation is that heterogeneity of treatment effects across studies is common and should be incorporated into the analysis. The random effects model incorporates this heterogeneity, however small, in the analysis of the overall efficacy of the treatment. The method estimates the magnitude of the heterogeneity, and assigns a greater variability to the estimate of overall treatment effect to account for this heterogeneity. In principle, we can extend the model to include pertinent covariate information [2]. Utilizing covariate information may substantially reduce the heterogeneity of effects and thus allow for more specific therapeutic recommendations. This is often difficult in practice, however, since covariate information may be missing for some studies. Improvement in publication standards for medical reporting and further methodological work for handling missing covariate information are needed to strengthen our ability to combine results from clinical studies.

For estimating the overall treatment effect and the variation of effects across studies, our results suggest that the weighted noniterative method is an attractive procedure because of the comparability of its estimates with those of the maximum likelihood methods and because of its relative simplicity. On

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the other hand, the unweighted method which ignores differences in sample sizes yields estimates that often differ from the estimates of the other methods.

A problem in pooling data we have not addressed here is that of publication bias. This problem relates to studies being executed, but not reported, usually because treatment effect has not been found. Reviewers generally recount those studies that appear to be worthwhile and discount those that are unpublished or are not in agreement with a favored group of studies. The method we describe here represents a systematic, quantitative pooling of available data to resolve controversies about a treatment effect. With each individual controversy, unpublished information may be elicited and along with recent findings the method can be used to update the results.

In all our work we assume that the sampling variances are known, although in reality we estimate them from the data. Further research needs to be done in this area as there are alternative estimators that might be preferable to the ones we use. For instance, if the sample sizes in each study are small, then sampling variances based on pooled estimates of the proportions in the treatment and control groups might be better than the ones based on estimates of proportions from the individual studies. Another alternative is to shrink the individual proportions towards a pooled estimate before calculating the variances. Further investigation is needed before one single method emerges as superior.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 0078

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Jennifer,

I hope you had a nice weekend. The responses to the questions are attached, which are (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

Thank you again for the (b)(4) Although minor, there

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

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To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image010.png@01D8C615.482E0CE0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C646de0e164334b6fa3ed08da902a9383%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637980809805223253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YBk7QkTPBGO2ioFUitPI4EwNfrWAJIeESon8lCkmrfM%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Please provide (b)(4) documents by 8 AM September 6, 2022. I'm also available for questions regarding this request.

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

All good, we're always waiting and willing!

Thanks,

Justin

[cid:image003.png@01D8D331.F9854A70]<http://secure-web.cisco.com/1gkB5ro6fNrQfhx27i2yXffaa4XpCcI5AUMDlWCWMM06NWf_UFch3vj4CKLpUJN5Wg3jQAXNI2ljh74KlEaDLRMX--9vh4KqTmIstH47R4FgvrjPDsOPg_LOAlsNa333tz9UX6-Gkts0Yl52NsxOb-tbmn1mivXNbxOZkyM1znUHC48VNZRsKbsKtsKv-d8yM/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1gkB5ro6fNrQfhx27i2yXffaa4XpCcI5AUMDlWCWMM06NWf_UFch3vj4CKLpUJN5Wg3jQAXNI2ljh74KlEaDLRMX--9vh4KqTmIstH47R4FgvrjPDsOPg_LOAlsNa333tz9UX6-Gkts0Yl52NsxOb-tbmn1mivXNbxOZkyM1znUHC48VNZRsKbsKtsKv-d8yM/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4) are attached to this email for your review.

Thanks,

Justin

[cid:image004.png@01D8D331.F9854A70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981164112%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gN18pG0poyqW0njZ%2FqqKqsink8WnEwGWEw94pkMohBg%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dMtpztD4aXZhAUtxppCDzG94ER1vwlRI1kw2hLVWsAY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4301 Released by CDRH on 10-15-2024

(b)(4)

Thanks,

Justin

[cid:image007.png@01D8D331.F9854A70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nF0GB%2FXwysfDkxBieK7vLt%2FTOZTV6cySb%2Fwgyx3ej0A%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

I hope you had a nice weekend. (b)(4) (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

[cid:image009.png@01D8D331.F9854A70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5h%2BogPYsUJaOfCE%2BtSo9cxzBVJZwJVIuR6ksX5Qq4Ls%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5h%2BogPYsUJaOfCE%2BtSo9cxzBVJZwJVIuR6ksX5Qq4Ls%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image015.png@01D8D331.F9854A70]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=4wZ1DFFPDhBIeN9ESwuTQvmTeVwbH%2B4SmBY527FrsEI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

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Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=4wZ1DFFPDhBIeN9ESwuTQvmTeVwbH%2B4SmBY527FrsEI%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Web: http://secure-web.cisco.com/1WmrbSbBCK-LITZNc7w2NOsAJpTlZXxSNReerf9jJo0gROKBwpGUvsQO2m8Z6_4Q3hzWmJbPnfWeBruQFLHLD-Mu5B9UYxStlmKRPI68_XtCMeGR3ZhznrnkBwN7KRRm1YqcmU68jDL67H00ctdxNNvodeHE0CCty6WF65horSqbUzzrptYdhWpElZvqjRRU-/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

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Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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	Title: **FIBERGRAFT® BG PUTTY PPQ Report**	
	Document No: (b)(4)	Revision No: (b)(4)

Approvals	Date
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CONDUIT™ ALIF System

Surgical Technique

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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Indications and Contraindications

Indications

The CONDUIT ALIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT ALIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors in the region of implant anchoring
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product Overview

CONDUIT™ ALIF Implant

Lattice Structure Geometry

- ~ 80% porosity[1]
- ~ 700 µm diamond pore size[2]

Rough surface

Rough elevated surface

Grafting

Designed to allow for bone grafting

Various sizes

Various footprint sizes for maximum endplate contact

- 34 x 25 mm (S)
- 37 x 27 mm (M)
- 40 x 29 mm (L)

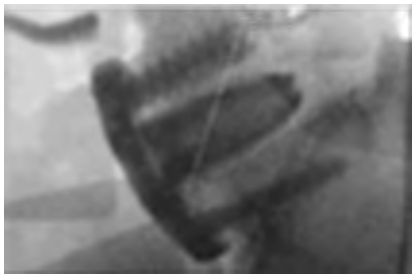
Various heights

6 heights in 2 mm increments

- 8-18 mm, depending on lordosis angle

Several angles

5°, 10°, 15° and 20° lordosis angle for spinal alignment and sagittal balance



X-Ray lateral view. ALIF implant used in conjunction with anterior plate.

X-Ray lateral view. High lordotic (20°) ALIF implant used in conjunction with supplemental posterior pedicle screw fixation.

1. VAL2016-043 Strut diameter summary rev 0.
2. EIT Scaffold characteristics P773 Signed Report_DM 20180417.

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CONDUIT ALIF Implants

footprint S

34 mm x 25 mm (Width x Depth)

	Lordosis			
Height	5°	10°	15°	20°
8mm*	AUI10834			
10 mm	AUI11034	AUI31034	AUI51034	
12 mm	AUI11234	AUI31234	AUI51234	AUI71234
14 mm	AUI11434	AUI31434	AUI51434	AUI71434
16 mm		AUI31634	AUI51634	AUI71634
18 mm		AUI31834	AUI51834	AUI71834

*Implants only have the anterior Inserter interface connection

footprint M

37 mm x 27 mm (Width x Depth)

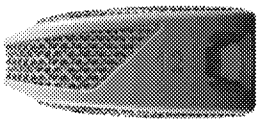
	Lordosis			
Height	5°	10°	15°	20°
8 mm*	AUI10837			
10 mm	AUI11037	AUI31037	AUI51037	
12 mm	AUI11237	AUI31237	AUI51237	AUI71237
14 mm	AUI11437	AUI31437	AUI51437	AUI71437
16 mm		AUI31637	AUI51637	AUI71637
18 mm		AUI31837	AUI51837	AUI71837

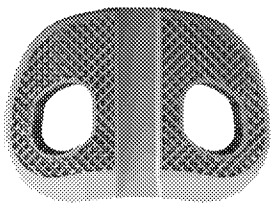
*Implants only have the anterior Inserter interface connection

footprint L

40 mm x 29 mm (Width x Depth)

	Lordosis			
Height	5°	10°	15°	20°
8 mm	AUI10840			
10 mm	AUI11040	AUI31040	AUI51040	
12 mm	AUI11240	AUI31240	AUI51240	AUI71240
14 mm	AUI11440	AUI31440	AUI51440	AUI71440
16 mm		AUI31640	AUI51640	AUI71640
18 mm		AUI31840	AUI51840	AUI71840





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Trials

footprint S

34 mm x 25 mm (Width x Depth)

	Lordosis			
Height	5°	10°	15°	20°
8 mm*	AET10834	AET30834		
10 mm	AET11034	AET31034	AET51034	
12 mm	AET11234	AET31234	AET51234	AET71234
14 mm	AET11434	AET31434	AET51434	AET71434
16 mm		AET31634	AET51634	AET71634
18 mm		AET31834	AET51834	AET71834

*Trials only have the anterior Inserter interface connection

footprint M

37 mm x 27 mm (Width x Depth)

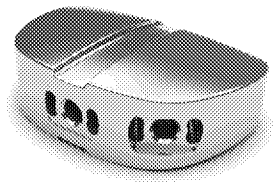
	Lordosis			
Height	5°	10°	15°	20°
8 mm*	AET10837			
10 mm	AET11037	AET31037	AET51037	
12 mm	AET11237	AET31237	AET51237	AET71237
14 mm	AET11437	AET31437	AET51437	AET71437
16 mm		AET31637	AET51637	AET71637
18 mm		AET31837	AET51837	AET71837

*Trials only have the anterior Inserter interface connection

footprint L

40 mm x 29 mm (Width x Depth)

	Lordosis			
Height	5°	10°	15°	20°
8 mm	AET10840			
10 mm	AET11040	AET31040	AET51040	
12 mm	AET11240	AET31240	AET51240	AET71240
14 mm	AET11440	AET31440	AET51440	AET71440
16 mm		AET31640	AET51640	AET71640
18 mm		AET31840	AET51840	AET71840



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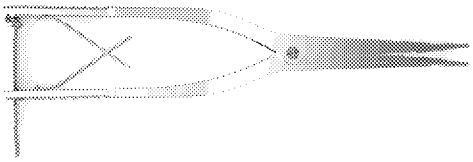
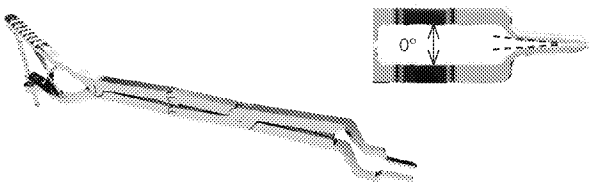
Paddle Distractor

Height	Ref
8 mm	AET10208
10 mm	AET10210
12 mm	AET10212
14 mm	AET10214
16 mm	AET10216
18 mm	AET10218

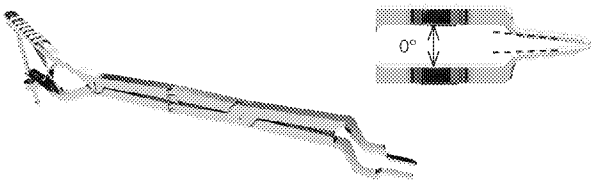
AFT10100 Offset Distractor Forceps



AET30120 Trial-Implant Guide Small



AET30121 Trial-Implant Guide Large



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AET20101	Trial Inserter
AET30101	Implant Inserter
PET00920	Straight handle
PET00910	T-handle
PET60251	Slap hammer
PET60250	Hammer
AEC00101	ALIF Instrument Tray

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000174

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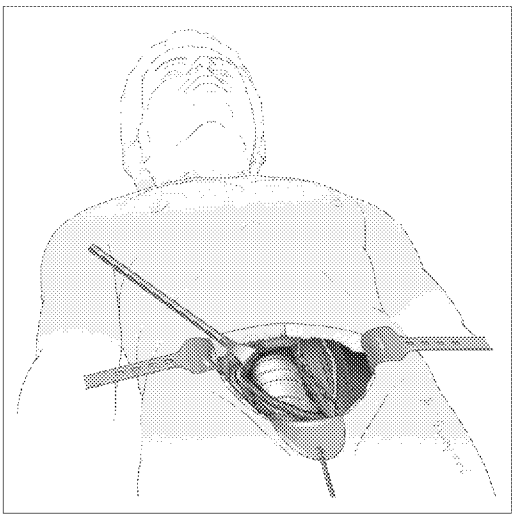
Preparation and Approach

For an anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position (Figure 1).
The surgical approach depends on the level to be treated. Locate the correct operative level and incision site by taking a lateral fluoroscopic view.
It is recommended to expose the operative level through a standard retroperitoneal approach (Figure 1). However other approaches may be indicated based on the patient's anatomy and pathology. Expose the operative level such that there is sufficient space on either side of the vertebral midline.

Fig 1

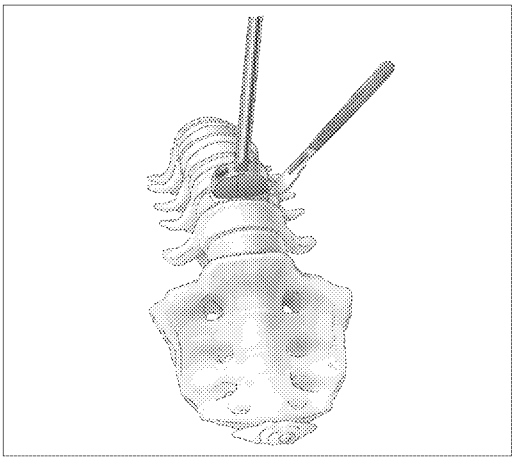


Discectomy

Create an annulotomy centered on the midline and wide enough to accommodate the CONDUIT ALIF Implant. Optionally, a trial implant (Figure 2) may be used as a template to indicate the width of the annular window.

Remove disc material through an incision in the annulus fibrosus. Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.
Adequate preparation of the endplates without compromising the structural integrity is important to enable the access of an appropriate vascular supply to the bone graft to enable fusion.
Once the endplates have been prepared, complete additional surgical procedures.

Fig 2



Precautions:

- Retain as much of the anterolateral, lateral and posterior annulus as possible in order to provide the necessary stability of the instrumented segment.
- It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during implant insertion and interference with bone in-growth.
- Overly aggressive preparation can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Distraction

Sufficient distraction should be applied to restore intervertebral height and provide stability of the implant. For this purpose, Offset Distractor Forceps (Figure 3) and/or Paddle Distractors (Figure 4) can be used.

When using the Offset Distractor Forceps, carefully apply parallel distraction by using both instruments on each side of the intervertebral space.

The Paddle Distractors are available in heights of 8 mm to 18 mm in 2 mm increments. It is advised to start with the smallest size Paddle Distractor to avoid over distraction. Insert the Paddle Distractor parallel to the intervertebral space and carefully turn clockwise to open up the disc space to avoid injury of the endplates. Proceed with one size bigger until sufficient distraction is achieved.

Distraction of the segment is essential for restoration of disc height, opening of the neural foramina, and indirect decompression of the canal. Achieving appropriate fit, fill, and distraction of the disc space will also enhance the initial stability of the CONDUIT ALIF Implant.

Precautions:

- In order to minimize the risk of endplate and to reduce the risk of subsidence and nerve damage, it is essential that both tips of the Offset Distractor Forceps instruments are placed parallel and to the posterior margin of the vertebral body within the intervertebral disc space. In addition, inserting the Offset Distractor Forceps and / or Paddle Distractor instruments too deep could lead to nerve damage. In order to ensure this, fluoroscopy is advised during insertion of both Offset Distractor Forceps instruments and / or during insertion of Paddle Distractor instruments.
- It is important to not over distract the segment to prevent injury of ligamentous and neural structures.
- Under-distraction may lead to insuffcent height restoration and soft tissue damage.

Fig 3

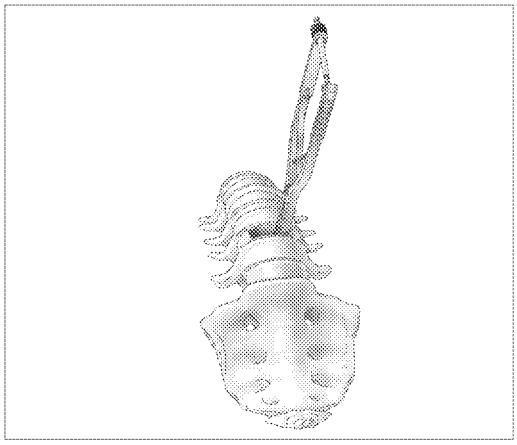
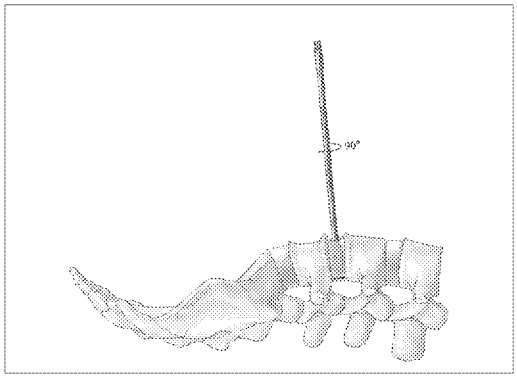


Fig 4



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Trial - Inserter connection

Choose an appropriately sized trial. Trials are available matching footprint, height, and angle of each implant.

Assembly Instructions Trial Inserter (Figure 5):

- Make sure the Trial Inserter is properly assembled by inserting the inner shaft into the Trial Inserter tube. The components are engaged by turning the knob of the inner shaft clockwise on the back of the yellow handle.
- Position the two tips of the Trial Inserter into the two outer openings of the trial and attach the trial to the Inserter by turning the knob of the inner shaft clockwise. Depending on the approach and size of the trial being used, the anterior or antero-lateral trial interface can be used.

Fig 5

Precautions:

- Ensure that all disc material is removed to prevent displacement of disc material into the spinal canal during trial insertion.
- Inserting the trial too deep could lead to nerve damage.
- Using an inappropriately sized trial could lead to endplate damage.

Note: Implants are slightly higher (0.25 mm) than the trials due to the implant's porous structure.

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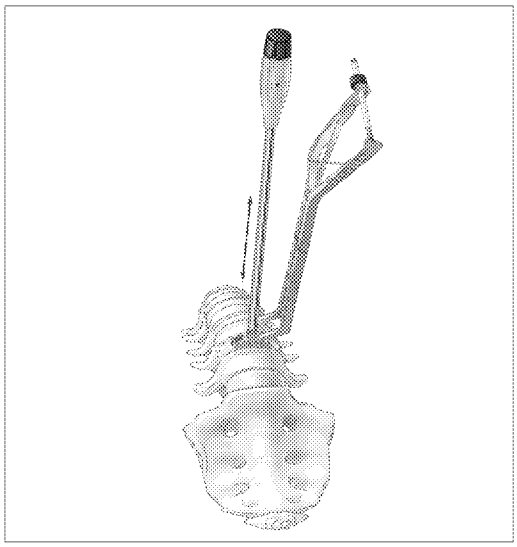
Trial for Implant Size

The Trial-Implant Guide (Figure 6) is used to guide the trial into the disc space. The blades of the Trial-Implant Guide match the slits in the trial to facilitate the trial insertion. It is recommended to mark the vertebral midline on the anterior surface of the vertebral body; the central line of the blades should be aligned with the anterior midline of the vertebral body. Depending on the size or lordotic angle of the trial, the Trial-Implant Guide with small or large angle can be chosen to fit the trial trajectory. Use the Trial-Implant Guide Small for trials and implants with an angle from 0-10° and the Trial-Implant Guide Large for trials and implants with heights ≥14 mm and angles from 10-20°. Use fluoroscopy during trial insertion and to confirm final position and fit of the trial.

Fig 6



Precautions:

- **Do not leave the trial in the disc space.**
- **Insufficient disc space preparation may compromise vascular supply to the bone graft.**
- **Be aware of soft tissue or blood vessels that may be in the pathway of the trial or cause possible interference with retractor blades.**
- **Do not use the Trial-Implant Guide to distract the intervertebral motion segment. It is only intended to be used for guiding purposes of the trial or implant.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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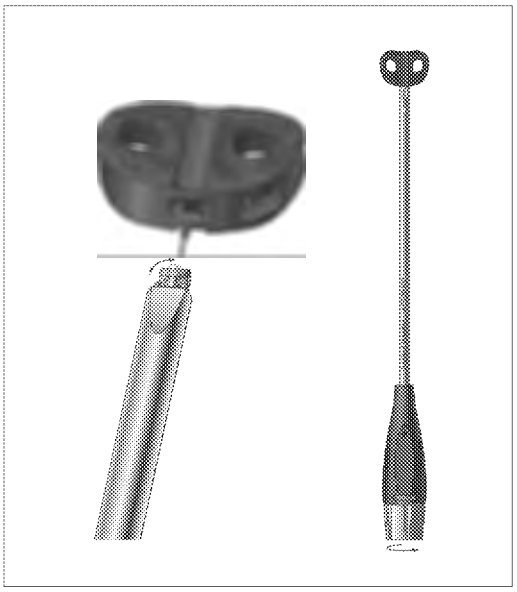
Implant - Inserter connection

- Select the CONDUIT ALIF Implant that corresponds to the footprint, height and angle chosen using the trial in the previous steps.
  To facilitate selection of the implant, the trials are labelled with the height, lordotic angle and footprint of the implant. For more information about the implant options, see pages 4 to 5 in this technique guide. Open the sterile packaging of the implant size that was determined using the trial.
- Instructions Implant Inserter (Figure 7):
  1. Insert knob at top of black handle
  2. Insert inner shaft into Implant Inserter handle, centrally align key into the slot until flush with Implant Inserter handle and tighten knob clockwise until thicker portion of inner shaft is flush with distal tip of Implant Inserter
  3. Place T-bar into opening, turn 90° and tighten clockwise (Figure 7)

Fig 7



Note: The implant can be attached at two positions; depending on the approach and size, the anterior or antero-lateral implant interface can be used.

Implant Insertion

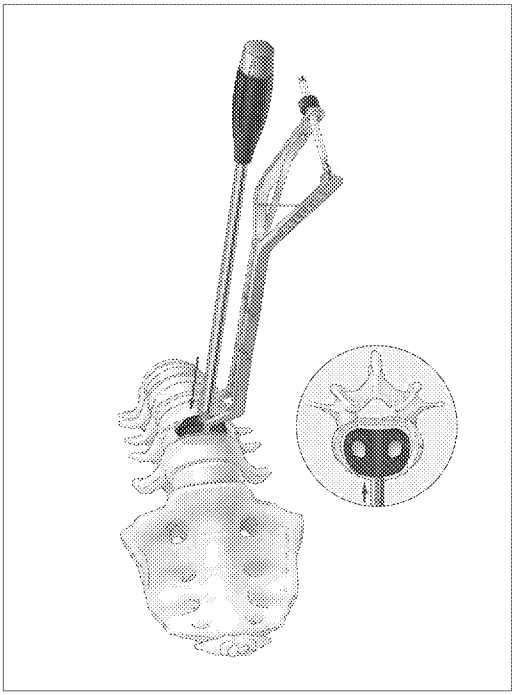
The implant is introduced with the Trial-Implant Guide in-situ in the same way as the trial. Again, verify position under fluoroscopy. The use of fluoroscopy is recommended during all implantation steps to ensure proper positioning.

Final Implant positioning

The implant should cover the endplate as much as possible and match the endplate concavity (Figure 8). Once proper placement is confirmed using fluoroscopy, proceed with the following steps:

1. Turn knob at end of shaft counter clockwise, (approximately ~7 rotations)
2. Then, turn Implant Inserter 90° and detach from implant, pull Implant Inserter gently backwards, detaching the T-bar connection from the implant

Fig 8



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Supplemental Fixation

The CONDUIT ALIF Implant is intended to be used with supplemental fixation (e.g., anterior plating, pedicle screws, or other posterior fixation devices).

Implant Removal / Revision

The CONDUIT ALIF Implant is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to adjust the position, revise or remove the CONDUIT ALIF Implant, connect the Implant Inserter to the implant:

Option 1:
Use the slotted Hammer to facilitate removal of implant.

Option 2:
Use the Slap hammer to facilitate removal of implant (Figure 9). Attach Slap hammer to knob of the Implant Inserter shaft and slide Slap hammer up and down to remove implant.

Fig 9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Description

The CONDUIT ALIF Cage is an implant made from a titanium alloy for the anterior stabilization of the lumbar spinal column using an Anterior Lumbar Interbody Decompression and Fusion (ALIDF) surgery. CONDUIT ALIF Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

The 3D Printed CONDUIT ALIF Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Material

The CONDUIT ALIF Cage is made from titanium 6-aluminum 4-vanadium alloy (ASTM-F3001). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

Intended use / Indications

The CONDUIT ALIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT ALIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors in the region of implant anchoring
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device. Neurological difficulties include bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions.
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Each patient's record shall document the implant used (article number, description and lot number).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000181

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- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use an implant if its packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

Storage, inspection and resterilization

Storage
The implant is individually packed in protective packaging that is labeled according to its contents. The implant is sterilized with gamma sterilization (25 kGy minimum).
- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment).

Disinfection/cleaning
The implant is not designed to be disinfected or cleaned by the user.

Resterilization
The implant is not designed to be resterilized by the user.

Magnetic Resonance (MR) compatibility
Non-clinical testing has demonstrated that the CONDUIT ALIF Cage is MR Conditional and can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to:
  — 4,000 G/cm (40 T/m) for 1.5 T and 3T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  — 2.0 W/kg for 15 minutes of scanning in First Level Controlled Operating

1.5 T and 3T RF heating
Under the scan conditions defined above, the CONDUIT ALIF Cage is expected to produce a maximum temperature rise of less than 5.0 °C after 15 minutes of continuous scanning.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact
In non-clinical testing, the image artifact caused by the device extends approximately 3.3 cm from EIT's ALIF device when imaged with a gradientecho pulse sequence in a 3 T MRI.

Procedure
Only implant the CONDUIT ALIF Cage with the applicable EIT ALIF instruments.
Note: The EIT ALIF instruments are available from the manufacturer at any time.

Preoperative
The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component(s) and the dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:
- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warnings:
Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.
- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed,

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or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities. Corrective surgery may be necessary if the implant fails.
- Corrective surgery may be necessary if the implant fails.
- The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

Intraoperative
- Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.
- Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

Warnings:
Never use implants if the packaging is damaged.
Never use implants that are past their expiration date.

The CONDUIT ALIF Cage is inserted via the anterior approach, which is largely consistent with the principle of ALIF (Anterior Lumbar Interbody Fusion). The surgical technique manual should be carefully followed. Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.
- If necessary, use the Disc Space Opener to open up a severely collapsed disc.
- Perform a standard anterior lumbar decompression and discectomy using preparation instruments including rongeurs and curettes. The Shaver may be used to remove disc material and prepare the endplates.
- In case of inadequate distraction, use the appropriate size (paddle) Distractor or Distractor Pliers. In case of using the (paddle) Distractor, it should be considered to start with the smallest size to avoid over-distraction.
- Determine the appropriate implant size with the Trial.
- Place the implant into position using the Implant Inserter. If necessary, slightly adjust the location of the implant using the Impactor under X-ray control.

This device is intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g., using posterior pedicle screws and rods or anterior plate and screw system).

Warning: When performing cauterization around an implant, avoid contact with the implant.

Postoperative
- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

Revision surgery / Implant removal
The CONDUIT ALIF Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to correct the location, revise or remove the CONDUIT ALIF Cage, connect the Implant Inserter to the implant. Slide the Hammer along the Implant Inserter shaft and relocate/remove the implant using gentle taps of the Hammer.

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Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Note: For recognized legal manufacturer, refer to the product label.

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CONDUIT™ Cervical System

Surgical Technique

DePuy Synthes

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Indications and Contraindications

Intended use / Indications

The CONDUIT Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The CONDUIT Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

The CONDUIT Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Contraindications

Do not use the CONDUIT Cervical Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

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Product Overview

CONDUIT™ Cervical Implant

Lattice Structure Geometry
- ~ 80% porosity[1]
- ~700 µm diamond pore size[2]

Dome shaped
Dome shaped to fit endplate anatomy[3,4]

Rough surface
Rough elevated surface

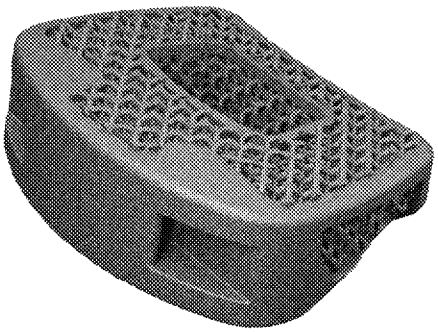
Grafting
Designed to allow for bone grafting

Various sizes
2 footprint sizes for maximized endplate contact
- Small (S) = 12 x 16 mm
- Large (L) = 14 x 18 mm

Various heights
6 heights in 1mm increments
- 5-10 mm

Several angles
4° and 8° lordosis angle for spinal alignment and sagittal balance

Lateral wedge
Lateral wedge design for maximal contact of the uncovertebral joint



References:

1. VAL2016-043 Strut diameter summary rev 0.
2. EIT Scaffold characteristics P773 Signed Report_DM 20180417.
3. Panjabi M, Duranceau J, Goel V, et al. Cervical Human Vertebrae. Quantitative Three-dimensional anatomy of the middle and lower regions. Spine 1991; 16:861-869.
4. EIT Implant Sizing Guides.

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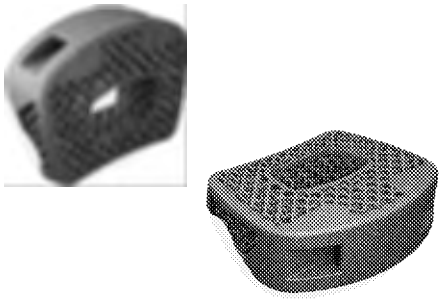
CONDUIT Cervical Implants

4° Angle

Height	Small	Large
5 mm	CUI4050S	CUI4050L
6 mm	CUI4060S	CUI4060L
7 mm	CUI4070S	CUI4070L
8 mm	CUI4080S	CUI4080L
9 mm	CUI4090S	CUI4090L
10 mm	CUI4100S	CUI4100L

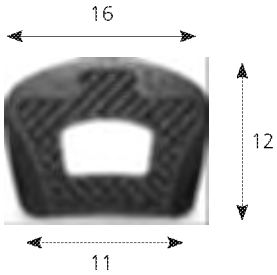


8° Angle

Height	Small	Large
5 mm	CUI8050S	CUI8050L
6 mm	CUI8060S	CUI8060L
7 mm	CUI8070S	CUI8070L
8 mm	CUI8080S	CUI8080L
9 mm	CUI8090S	CUI8090L
10 mm	CUI8100S	CUI8100L

H

S



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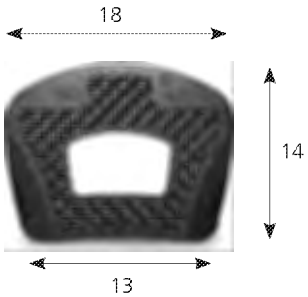

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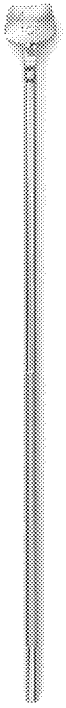
Trials

4° Angle

Height	Small	Large
5 mm	CET2050S	CET2050L
6 mm	CET2060S	CET2060L
7 mm	CET2070S	CET2070L
8 mm	CET2080S	CET2080L
9 mm	CET2090S	CET2090L
10 mm	CET2000S	CET2000L

8° Angle

Height	Small	Large
5 mm	CET2850S	CET2850L
6 mm	CET2860S	CET2860L
7 mm	CET2870S	CET2870L
8 mm	CET2880S	CET2880L
9 mm	CET2890S	CET2890L
10 mm	CET2800S	CET2800L



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CET30101	Inserter
CET30131	Slender Inserter
Part A	Inserter Tube
Part B	Gripper
Part C	Stopper
Part D	Tail wheel
Part E	Tube wheel

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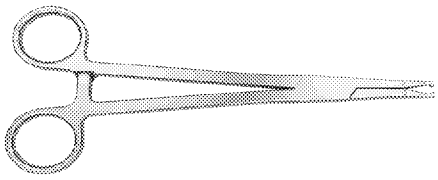
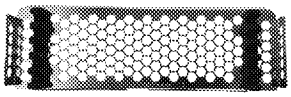
CET30201	Impactor

CET60100	Removal forceps



CEC00101	Cervical Instrument Tray - fits 15 trials

CEC00199	Cervical Tray Insert - fits 5 additional trials



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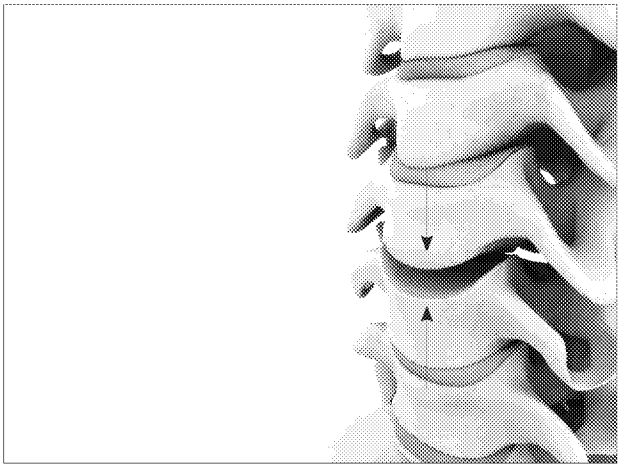
Preparation and Approach

Place the patient in the supine position with slight extension to facilitate access to the anterior cervical spine. Locate the correct operative level and incision site with fluoroscopy. Use the medial anterior approach for C2-T1 and dissect the affected disc space per the standard operating procedure for an anterior cervical discectomy and fusion. (Figure 1)

Figure 1



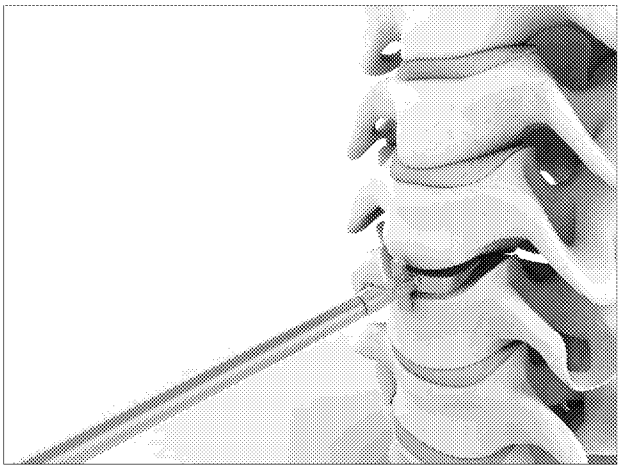
Discectomy and Endplate Preparation

Use a Caspar Distractor to distract the space. Perform microsurgical decompression to relieve all points of neural compression and prominent ventral spondylosis ridges, preserving the uncovertebral joints and subchondral bone as much as possible. Perform the discectomy using curettes, rongeurs, rasps, or high speed drills. The vertebral bony endplates need to stay intact and it is important to thoroughly remove the cartilaginous material from these surfaces. The implant is intended to laterally rest on the uncovertebral joints. Carefully prepare the disc space symmetrically to ensure an optimal width for an appropriate cage fit.

Determination of Cage Size

Choose an appropriately sized trial. "Lollipop" Trials are available matching footprint, height, and angle of each implant. Ensure the side marked "TOP" is cranial and position the Trial in the intervertebral disc space. Evaluate the fit by tactile feedback and, if necessary, fluoroscopy. Repeat until a suitable match is found and then remove the Trial. (Figure 2)

Figure 2



Note: Implants are slightly higher (0.25 mm) than the Trials due to the implant's off-set dome shaped porous structure.

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Inserter options

1. Inserter: Inserter-Forceps, no assembly required. (Figure 3)
2. Slender Inserter: Pencil shaped inserter, assembly required. (Figure 4)

Slender Inserter Assembly

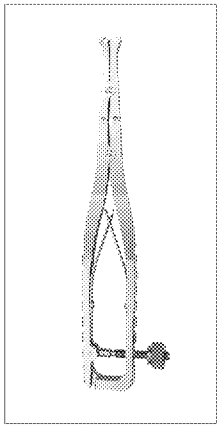
The Slender Inserter consists of five parts that must be assembled (Figure 5). Connect the Tube wheel (part E) to the Inserter Tube (part A). Slide the Gripper (part B) in the Inserter Tube (part A) and Tube Wheel (part E) to prevent the Tube Wheel from falling off of the Inserter Tube. Connect the Tail Wheel (part D) to the Tube Wheel (part E). Slide the Stopper (part C) into the Gripper and both wheels and turn the Tail Wheel clockwise to complete assembly. Ensure the wings at the front of the Stopper slide over the Gripper. Turn the Tail Wheel to change the position of the Stopper. Make sure the Gripper is in the open position by turning the Tube Wheel.

Implant - Inserter connection

Upon selecting the appropriate Trial, remove the implant from its sterile packaging.

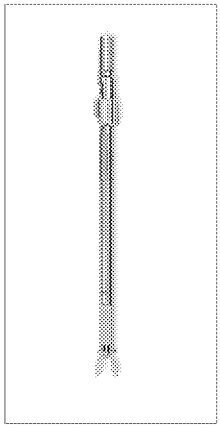
1. Attach the implant to the Inserter: (Figure 6)
   - Make sure the Inserter is in the open position (tips are apart).
   - Place the implant between the tips. Make sure the side marked 'TOP' on the implant is cranial.
   - Lock the implant with the grip notches between the tips by pressing the grips together and turning the wheel of the Inserter.
   - Confirm that the implant is securely connected to the Inserter.
2. Attach the implant to the Slender Inserter:
   - Make sure the Slender Inserter is in the open position (tips are apart), and the Stopper is located near the tube (turn Tail Wheel clockwise).
   - Place the implant between the tips. Make sure the side marked 'TOP' on the implant is cranial.
   - Lock the implant by rotating the Tube Wheel clockwise.
   - Set the preferred distance of the Stopper from the implant by turning the Tail Wheel.
   - Confirm that the implant is securely connected to the Inserter.

Figure 3



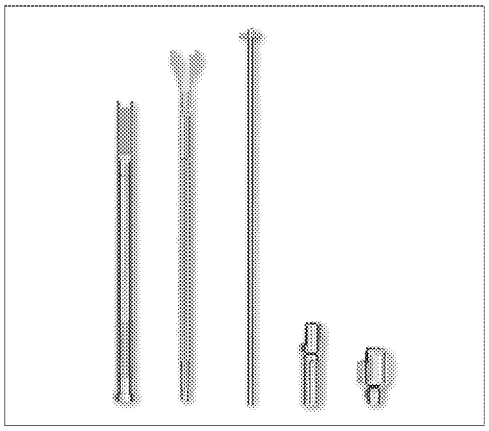
Inserter

Figure 4



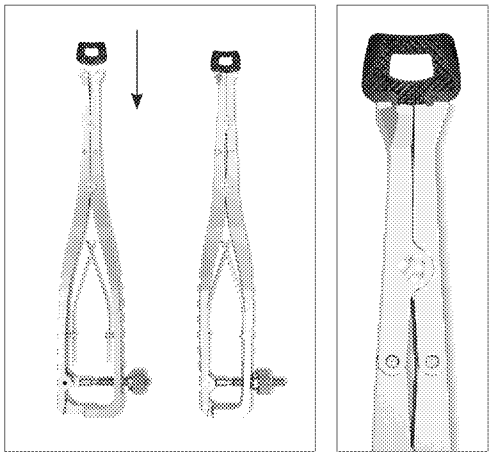
Slender Inserter

Figure 5



A B C D E

Figure 6



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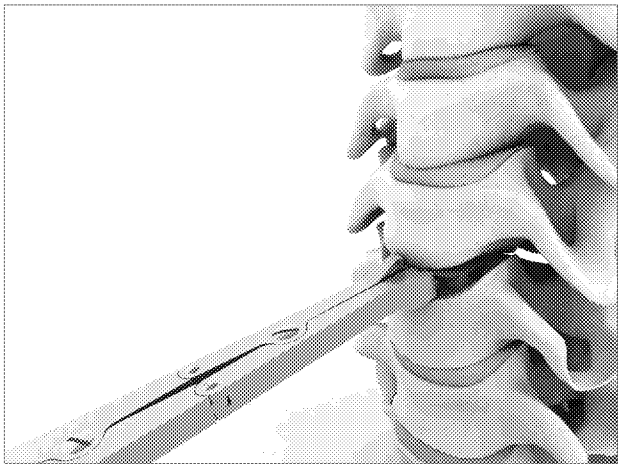
Implant Insertion

The implant should be packed with bone graft to facilitate the fusion process. Insert the implant into the intervertebral disc space. The implant should be positioned posteriorly to fit the concavity of the inferior endplate of the superior vertebral body. Confirm the position of the implant with fluoroscopy. The posterior edge of the implant should be at least 2 mm anterior to the dura. Detach the Inserter from the implant, by opening the Inserter Forceps (Figure 7) or turning the Tube Wheel counter clockwise to open up the tips of the Slender Inserter.

If repositioning is needed, the Impactor can be used to position the implant further into the vertebral disc space. The vertebral body stops of the Impactor allow the implant to be inserted up to 3 mm deep into the intervertebral space. The use of fluoroscopy is recommended during implantation to ensure proper positioning.

Figure 7



Completion of Surgery / Postoperative Care

After implanting the cage and removing the Caspar Distractor, close the wound. The use of the CONDUIT cervical cage does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.

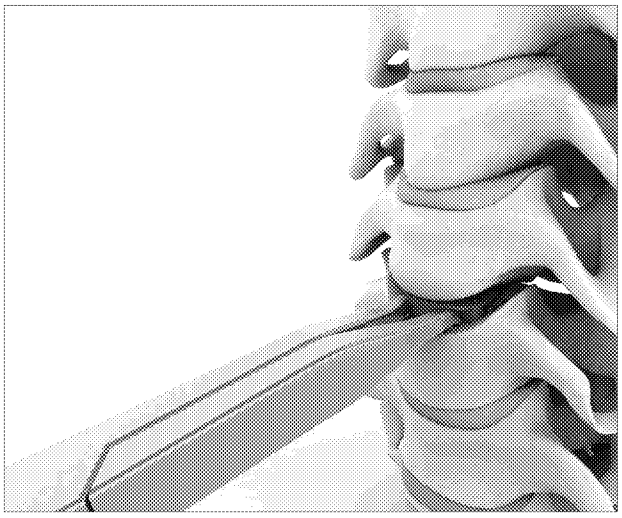
Implant Removal / Revision surgery

Removal with the Removal Forceps:

- Make sure the forceps are in the open position (tips are apart).
- Place the tips of the Removal Forceps into the implant and close the forceps. The tips should now grasp the implant inside the cavities.
- Remove the implant from the intervertebral disc space. (Figure 8)

Warning: Do not use the Removal Forceps for implantation. The lack of a stop could result in an error of placing the device too deep into the disc space resulting in spinal cord injury.

Figure 8



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Instructions for Use

Please ensure that you have understood these instructions for use before using the product.

Description

The CONDUIT Cervical Cage is an implant made from a titanium alloy for the anterior stabilization of the cervical spinal column using an Anterior Cervical Discectomy and Fusion (ACDF) surgery.
CONDUIT Cervical Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

The 3D Printed CONDUIT Cervical Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Material

The CONDUIT Cervical Cage is made from titanium 6-aluminum 4-vanadium alloy (ASTM-F3001). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

Intended use / Indications

The CONDUIT Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1.

The CONDUIT Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

Contraindications

Do not use the CONDUIT Cervical Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions.
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Under no circumstances may modular implant components from different suppliers be combined.
- Each patient's record shall document the implant used (article number, description and lot number).

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- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use an implant if its packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

Storage, inspection and resterilization

Storage
The implant is individually packed in protective packaging that is labeled according to its contents. The implant is sterilized with gamma sterilization (25 kGy minimum).
- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment).

Disinfection/cleaning
The implant is not designed to be disinfected or cleaned by the user.

Resterilization
The implant is not designed to be resterilized by the user.

Magnetic Resonance (MR) compatibility
Non-clinical testing has demonstrated that the CONDUIT Cervical Cage is MR Conditional and can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to 3,000 G/cm (30 T/m) for 1.5 T and 3T systems.
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 1.5 T and 3 T.

1.5 T and 3T RF heating
Under the scan conditions above, the CONDUIT Cervical Cage is expected to produce a maximum temperature rise of less than 0.5° C after 15 minutes of continuous scanning.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact
In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 1.7 cm from the device.

Procedure
Only implant the CONDUIT Cervical Cage with the applicable EIT cervical instruments.
Note: The EIT cervical instruments are available from the manufacturer at any time.
Preoperative
The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component(s) and their dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component(s)
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:
- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warning: Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

Warning: The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.
- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to

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obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

Intraoperative
Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.

Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

Warning: Never use the implants if the packaging is damaged.

Warning: Never use implants that are past their expiration date.

The CONDUIT Cervical Cage is implanted using a standard anterior approach to the cervical spine. Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.

- Determine the appropriate implant size with the Trial.
- Place the implant into position using the Inserter.
- If necessary, slightly adjust the location of the implant using the impactor under X-ray control.

In cases of instability, consider supplemental internal fixation using a cervical plating system.

Warning: When performing cauterization around an implant, avoid contact with the implant.

Postoperative
- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

Revision surgery / Implant removal
The CONDUIT Cervical Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

The Removal Forceps can be used to grasp and remove the implant if necessary.

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

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Note: For recognized legal manufacturer, refer to the product label.

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Eisenbahnstrasse 84
78573 Wurmlingen
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For complaints reporting, please use the following contact details that are applicable:
Phone: +1-866-491-0974
Mail: depuyspineproductcomplaints@dpyus.jnj.com

www.depuysynthes.com

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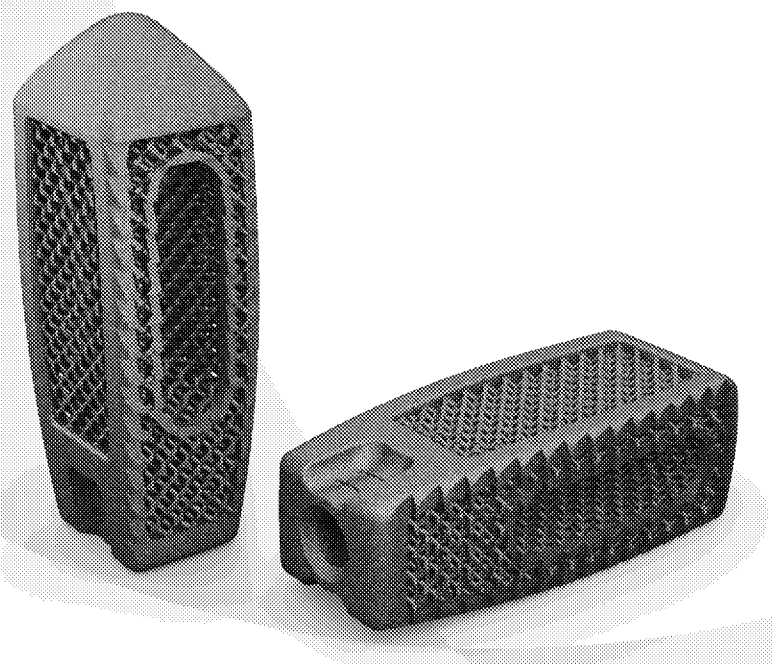
CONDUIT™ Straight TLIF / PLIF System

Surgical Technique



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Indications and Contraindications

Indications

The CONDUIT T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT T/PLIF

Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic Implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and Implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

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Product Overview

CONDUIT™ Straight TLIF / PLIF Implant

Lattice Structure Geometry

- ~ 80% porosity[1]
- ~ 700 µm pore size[2]

Smooth introduction

Bullet shape and solid edges allow for a smooth introduction along soft tissues and adaptation to endplate anatomy

Rough surface

Rough elevated surface

Grafting

Designed to allow for bone grafting

Footprint sizes:

- 9 x 22 mm
- 9 x 26 mm
- 9 x 30 mm
- 11 x 26 mm

Various heights

9 heights in 1 mm increments

- 7-15 mm

Several angles

4°, 8°, 12° and 18° lordotic angles for spinal alignment and sagittal balance

1. VAL2016-043 Strut diameter summary rev 0
2. EIT Scaffold characteristics P773 Signed Report_DM 20180417.

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Straight TLIF / PLIF Hyperlordotic Implants

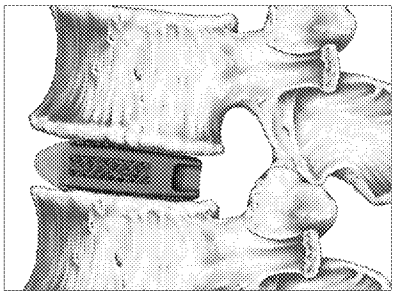
The hyperlordotic TLIF / PLIF interbody implants allow not only for the restoration of the natural height of the intervertebral disc, but also for the correction of lumbar sagittal and coronal imbalance from a direct posterior approach.

Implants in a variety of heights combined with two hyperlordotic angles are available to fit different anatomical variations.

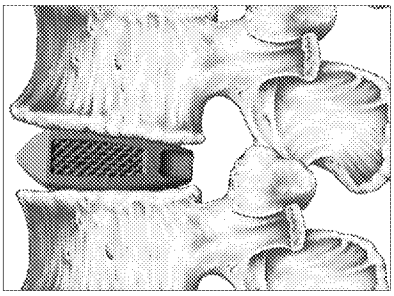
Lordotic Implant Options

The CONDUIT Straight TLIF / PLIF System has four lordotic implant designs available in various heights to achieve desired intervertebral height and lordotic angulation.

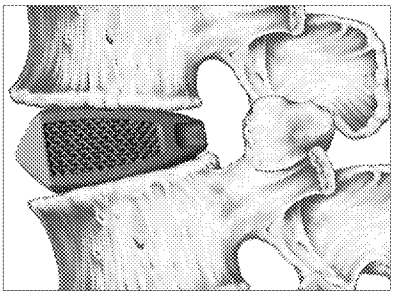
The pictures demonstrate the differences in lordosis between the 4°, 12° and 18° implants.



4°



12°



18°

Supplemental internal fixation not shown to provide clarity of implant lordosis. Images intended only to demonstrate the different degrees of lordosis.

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CONDUIT Straight TLIF / PLIF Implants

9 mm x 22 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm	PUI40702			
8 mm	PUI40802	PUI80802		
9 mm	PUI40902	PUI80902	PUI30902	
10 mm	PUI41002	PUI81002		
11 mm	PUI41102	PUI81102	PUI31102	PUI91102
12 mm	PUI41202	PUI81202		
13 mm	PUI41302	PUI81302	PUI31302	PUI91302
14 mm	PUI41402	PUI81402		
15 mm	PUI41502	PUI81502	PUI31502	PUI91502

9 mm x 26 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm	PUI40706			
8 mm	PUI40806	PUI80806		
9 mm	PUI40906	PUI80906		
10 mm	PUI41006	PUI81006	PUI31006	
11 mm	PUI41106	PUI81106	PUI31106	PUI91106
12 mm	PUI41206	PUI81206		
13 mm	PUI41306	PUI81306	PUI31306	PUI91306
14 mm	PUI41406	PUI81406		
15 mm	PUI41506	PUI81506	PUI31506	PUI91506

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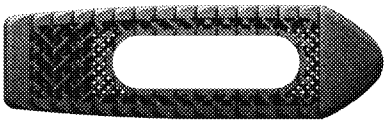
CONDUIT Straight TLIF / PLIF Implants

9 mm x 30 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm				
8 mm				
9 mm	PUI40910			
10 mm				
11 mm	PUI41110			
12 mm				
13 mm	PUI41310			
14 mm				
15 mm	PUI41510			



11 mm x 26 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm	PUI40726			
8 mm				
9 mm	PUI40926	PUI80926		
10 mm				
11 mm	PUI41126	PUI81126	PUI31126	
12 mm				
13 mm	PUI41326	PUI81326	PUI31326	
14 mm				
15 mm	PUI41526	PUI81526	PUI31526	

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Trials

9 mm x 30 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm	PET20710			
8 mm	PET20810			
9 mm	PET20910	PET80910	PET30910	
10 mm	PET21010	PET81010		
11 mm	PET21110	PET81110	PET31110	
12 mm	PET21210	PET81210		
13 mm	PET21310	PET81310	PET31310	
14 mm	PET21410	PET81410		
15 mm	PET21510	PET81510	PET31510	

6 mm x 30 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm				
8 mm				
9 mm				
10 mm				
11 mm			PET31106	PET91106
12 mm				
13 mm			PET31306	PET91306
14 mm				
15 mm			PET31506	PET91506

11 mm x 30 mm (Width x Length)

	Lordosis			
Height	4°	8°	12°	18°
7 mm	PET20730			
8 mm				
9 mm	PET20930	PET80930		
10 mm				
11 mm	PET21130	PET81130		
12 mm				
13 mm	PET21330	PET81330		
14 mm				
15 mm	PET21530	PET81530		

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Shavers

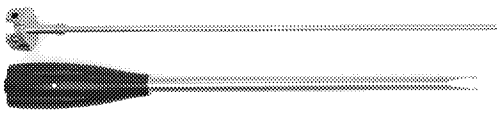
Height	Ref
7 mm	PFT10700
8 mm	PFT10800
9 mm	PFT10900
10 mm	PFT11000
11 mm	PFT11100
12 mm	PFT11200
13 mm	PFT11300
14 mm	PFT11400
15 mm	PFT11500

Distractors

Height	Ref
7 mm	PET10710
8 mm	PET10810
9 mm	PET10910
10 mm	PET11010
11 mm	PET11110
12 mm	PET11210
13 mm	PET11310
14 mm	PET11410
15 mm	PET11510

PET10050 Disc Space Opener

PET30102 Inserter



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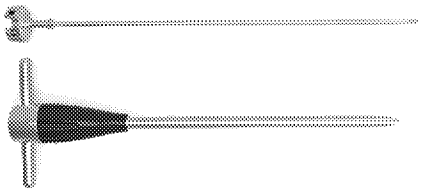
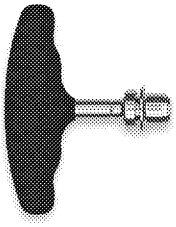
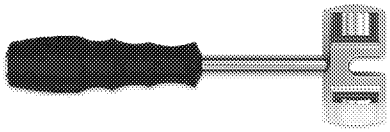
PET30101	T-Handle Inserter	
PET30200	Implant Pusher	
PET00920	Straight handle	
PET00910	T-handle	
PET60251	Slap-Hammer	
PET60250	Hammer	
PEC00101	Posterior IBF instrument tray large	

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Imaging appearance* of the CONDUIT Straight TLIF / PLIF Implants

The CONDUIT Implant is clearly visible in fluoroscopy, MRI and CT scans. The implant-endplate contact can be evaluated without disturbing scattering on CT scans or large imaging artefacts on MRI. The various lordosis angles and footprints in the CONDUIT portfolio allow for restoration of sagittal balance.

* Disclaimer: The CONDUIT Implant images displayed on this page are of CONDUIT Implants that are not FDA approved and not available in the USA.

X-Ray lateral view in a lab setting prior to implantation of supplemental posterior fixation.

MRI lateral view single level L4-L5/ direct postoperative

CT lateral view L4-L5 postoperative. Direct bone-implant contact and no disturbing scattering

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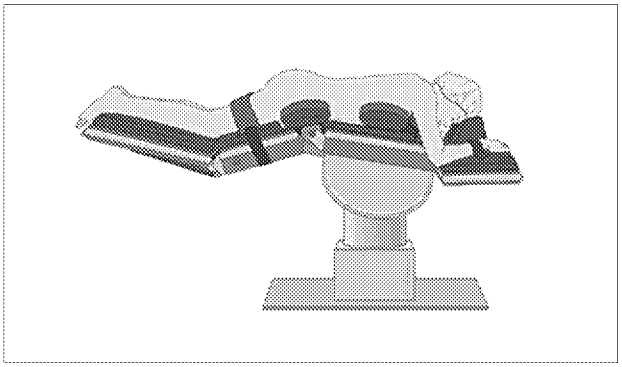
Preparation and Approach

Position the patient in a restored physiological lordosis and decompress the abdomen to minimize venous stasis. Locate the correct operative level with fluoroscopic views. (Figure 1)

Figure 1



Discectomy

Make a standard incision, retract the muscle layer to view the desired segment, and perform sufficient laminotomy and medial or complete facetectomy. (Figure 2) Remove disc material through an incision in the annulus fibrosis. If desired, use the Disc Space Opener to access a severely collapsed disc. Shavers can be used to remove disc material and scrape the bony surface. (Figure 3) Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate preparation of the endplates without compromising the structural integrity is important to enable the access of an appropriate vascular supply to the bone graft to enable fusion.

Once the endplates have been prepared, complete additional surgical procedures.

Precaution: Injury to the bony endplates must be avoided as this may lead to implant subsidence.

Figure 2

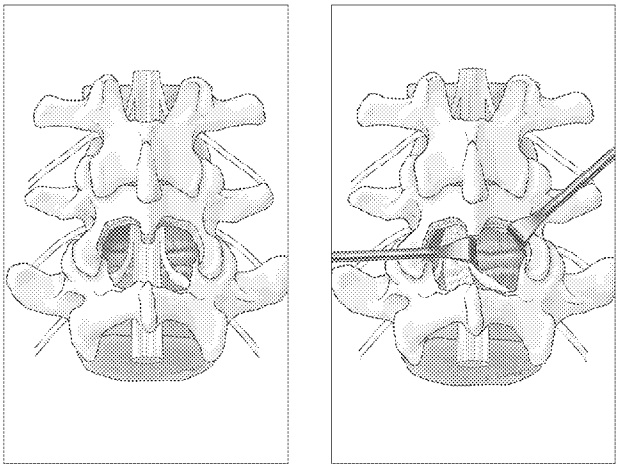
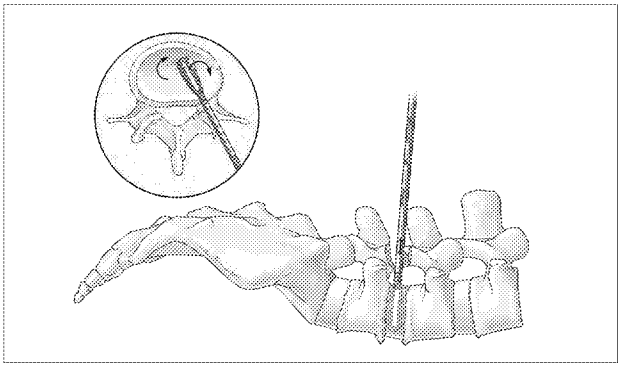


Figure 3



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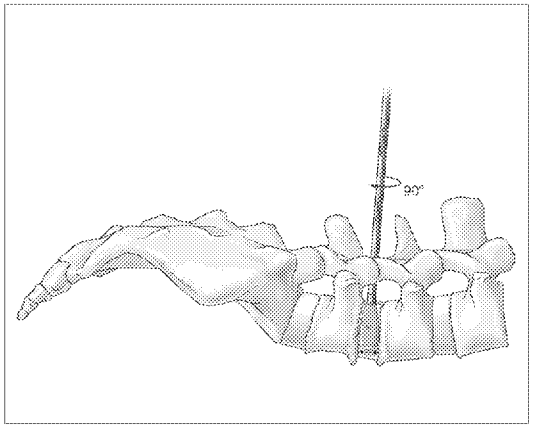
Distraction

Distraction opens the posterior disc space and promotes exposure both for decompression and delivery of the implant. Sufficient distraction should be applied to restore intervertebral height and provide stability of the implant. For this purpose, Distractors can be used. Distractors are available in heights of 7 mm to 15 mm in 1 mm increments. It is advised to start with the smallest size Distractor to avoid over distraction. Insert the Distractor parallel to the intervertebral space and carefully turn clockwise to open up the disc space to avoid injury of the endplates. Proceed with one size bigger until sufficient distraction is achieved. (Figure 4)

For further distraction and greater lordosis, 12° and 18° Trials are available. Both Distractors and Trials have depth markings.

Figure 4



Precautions:

- **Use caution while using Distractor/Shavers to avoid damage to the endplate.**
- **Excessive removal of the subchondral bone may weaken the vertebral endplate. Removal of the entire endplate may result in subsidence and a loss of segmental stability.**

Trial for Implant Size

Use Trials to determine the proper implant size. Trials are available in 4°, 8°, 12° and 18° lordotic angles. The 4° and 8° Trials can be introduced using the "impaction" technique. The 12° and 18° Trials should be introduced using the "insertion and rotation" technique.

The tips of all hyperlordotic Trials should be positioned near the anterior edge of the adjacent vertebral bodies before rotating clockwise. This ensures the strongest vertebral endplate bone is used to distract and achieve lordosis. Fluoroscopy, depth markings on the Trial head, and tactile feedback can help confirm the position and fit of the Trial.

Precaution: **Be aware of soft tissue, blood vessels or neural elements that may be in the pathway of the Instruments or cause possible interference with retractor blades.**

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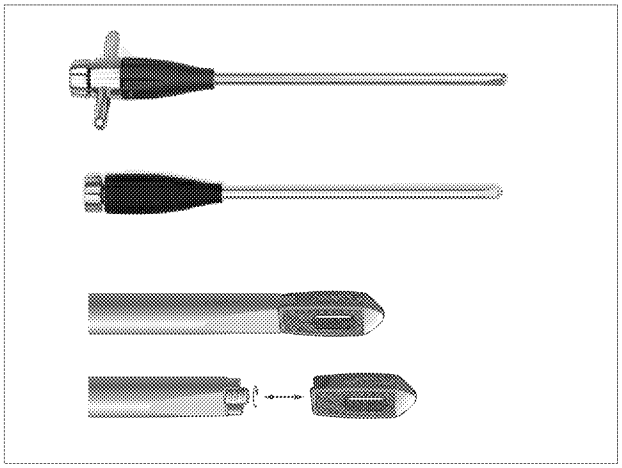
Implant - Inserter connection

- Select the CONDUIT Straight TLIF / PLIF Implant that corresponds to the footprint, height and angle chosen using the Trial in the previous steps. To facilitate selection of the implant, the Trials are labeled with the height, lordotic angle and footprint of the implant.
- Ensure the inserter is properly assembled by inserting the Inner Shaft into the Inserter Tube. Tighten the knob a few turns on the back of the handle to engage the components. (Figure 5)
- Remove the implant from its sterile packaging. When using a single implant in an oblique approach, it is advised to use the largest possible footprint that fits the anatomy. The implant must be packed with bone graft to facilitate the fusion process.
- Align the tips of the Inserter with the notches on the medial and lateral sides of the implant. Secure the implant onto the Inserter.

Figure 5



Implant Insertion: Impaction Technique

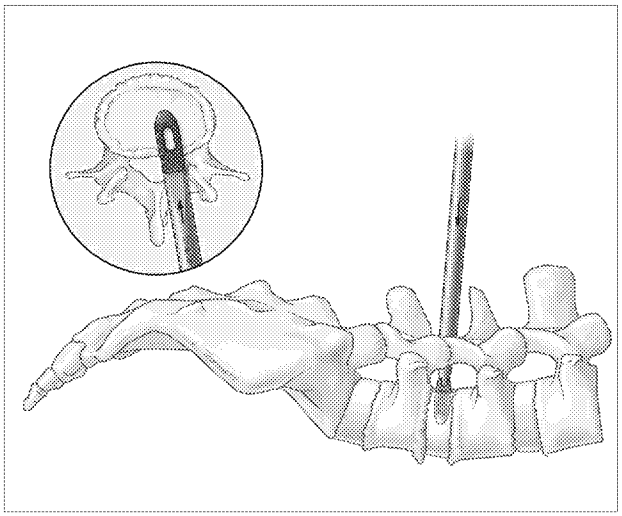
Insert the implant into the disc space, ensuring that the orientation of the implant is correct and that the implant is parallel to the endplates. (Figure 6) Controlled and light hammering on the Inserter may be required to advance the implant into the intervertebral disc space. If using two implants, be sure not to cross the midline. Intraoperative imaging and the markings on the shaft of the Inserter will confirm proper depth of the implant.

If using the transforaminal insertion technique, ensure that the implant is positioned across the midline in both the sagittal and coronal planes.

Use fluoroscopy during implant insertion and to confirm final position of the implant.

Precaution: Be aware of soft tissue, blood vessels or neural elements that may be in the pathway of the implant as the porous structure may increase the risk of adherence.

Figure 6



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Implant Insertion: Insertion and Rotation Technique

The use of fluoroscopy is recommended during all implantation steps to ensure proper positioning.

Horizontally position the handle of the Inserter and introduce the implant on its side to avoid overdistracting the segment. Intraoperative imaging and the markings on the shaft of the Inserter will confirm proper depth of the implant. The implant should be positioned near the anterior edge of the adjacent vertebral bodies. (Figure 7) Confirm the proper position of the implant and rotate the Inserter handle 90° clockwise to turn the implant vertically. (Figure 8) The upper and lower rough implant surfaces are slightly more off-set than the medial and lateral porous sides of the implant and should be in direct contact with the endplates in its final position.

Precaution: Be aware of soft tissue, blood vessels or neural elements that may be in the pathway of the implant as the porous structure may increase the risk of adherence.

Final Implant Positioning

The implant should be positioned as far anteriorly as possible in the anteriorposterior alignment. (Figure 9) Verify position under fluoroscopy. Once proper placement is confirmed using fluoroscopy, detach the Inserter by turning the knob at the end of the shaft several times counter clockwise. If desired, an Implant Pusher is available to position the implant after the Inserter has been removed. (Figure 10) The Implant Pusher can also be used to impact the remaining autograft into the intervertebral space.

Figure 7

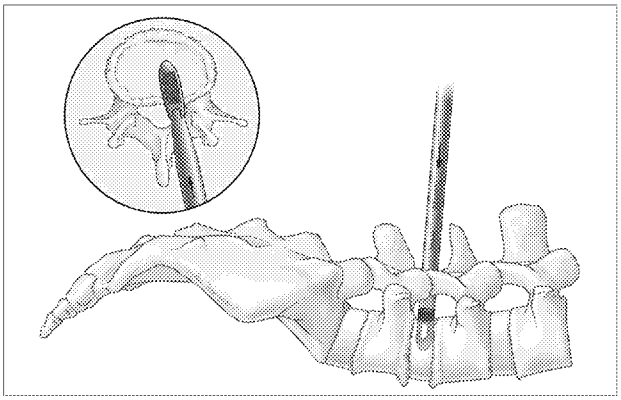


Figure 8

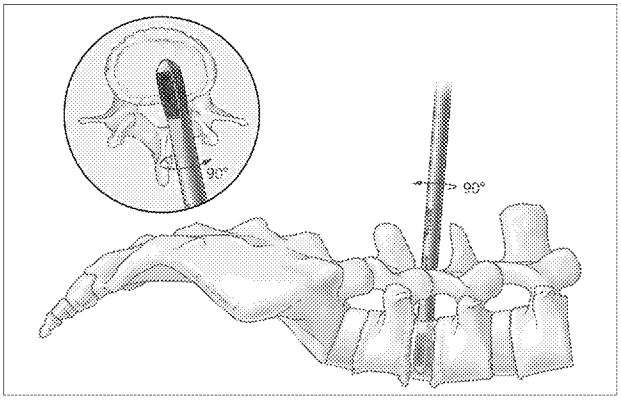


Figure 9

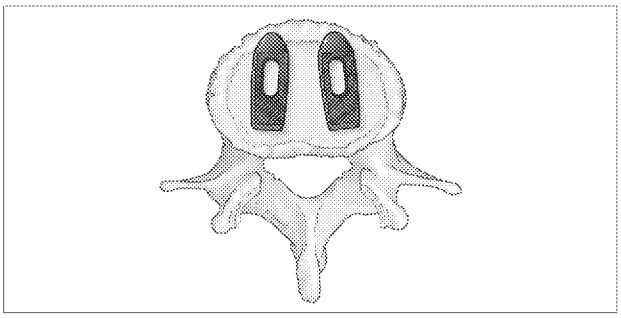
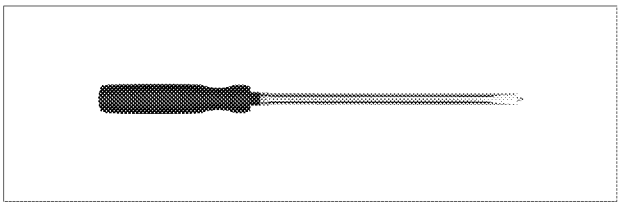


Figure 10



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Supplemental Fixation

The CONDUIT Straight TLIF / PLIF Implant is intended to be used with supplemental fixation (e.g., pedicle screws or other posterior fixation devices).

Implant Removal / Revision Surgery

The CONDUIT Straight TLIF / PLIF Implant is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

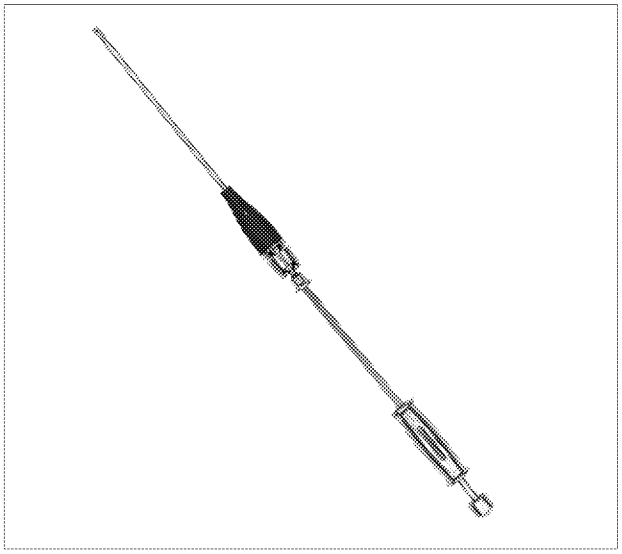
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to adjust the position, revise or remove the CONDUIT implant, connect the Inserter to the implant:

Option 1:
Use the slotted Hammer to facilitate removal of the implant. If a 12° or 18° implant is being removed, rotate the Inserter 90° to get the implant on its side.

Option 2:
Use the Slap Hammer to facilitate removal of the implant (Figure 11). Attach the Slap Hammer to the knob of the Inserter shaft and slide the Slap Hammer up and down to remove the implant.

Figure 11



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Description

The CONDUIT T/PLIF Cage is an implant made from a titanium alloy for the posterior stabilization of the lumbar spinal column using a Posterior Lumbar Decompression and Fusion (PLDF) surgery. CONDUIT T/PLIF Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

The 3D Printed CONDUIT T/PLIF Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Material

The CONDUIT T/PLIF Cage is made from titanium 6-aluminum 4-vanadium alloy (ASTM-F3001). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

Intended use / Indications

The CONDUIT T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT T/PLIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thuspreclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device. Neurological difficulties include bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Under no circumstances may modular implant components from different suppliers be combined.
- Each patient's record shall document the implant used (article number, description and lot number).

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- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use an implant if its packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

Storage, inspection and resterilization

Storage
The implant is individually packed in protective packaging that is labeled according to its contents. The implant is sterilized with gamma sterilization (25 kGy minimum).
- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment)

Disinfection/cleaning
The implant is not designed to be disinfected or cleaned by the user.

Resterilization
The implant is not designed to be resterilized by the user.

Magnetic Resonance (MR) compatibility
Non-clinical testing has demonstrated that the CONDUIT T/PLIF Cage is MR Conditional and can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to 3,000 G/cm (30 T/m) for 1.5 T and 3T systems.
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 1.5 T and 3 T.

1.5 T and 3T RF heating
Under the scan conditions above, the CONDUIT T/PLIF Cage is expected to produce a maximum temperature rise of less than 0.5° C after 15 minutes of continuous scanning.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact
In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 2.2 cm from the device.

Procedure
Only implant the CONDUIT T/PLIF Cage with the applicable EIT PLIF instruments.
Note: The EIT PLIF instruments are available from the manufacturer at any time.

Preoperative
The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component(s) and their dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component(s)
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:
- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warnings:
Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.
- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the Implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the Implant during the course of surgery may also contribute to early failure.

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- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

Intraoperative

- Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.
- Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

  Warnings:
  Never use implants if the packaging is damaged.
  Never use implants that are past their expiration date.

  The CONDUIT T/PLIF Cage is implanted using a standard posterior approach to the lumbar spine (PLIF) or a transforaminal approach to the lumbar spine (TLIF). Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.
- If necessary, use the Disc Space Opener to open up a severely collapsed disc.
- Perform a standard lumbar decompression and discetomy. The Shaver may be used to remove disc material if necessary.
- Perform adequate distraction using the appropriate size (Parallel) Distractor. It should be considered to start with the smallest size Distractor to avoid over-distraction.
- Using the "Impaction" surgical technique: Determine the appropriate implant size with the Trial. Place the implant into position using the inserter.
- Using the "Insert-rotation" surgical technique: Determine the appropriate implant size with the Lordotic Trial Distractor. Place the implant in position using the T-handle Inserter.
- If necessary, slightly adjust the location of the implant using the impactor under X-ray control.
- Posterior supplemental internal fixation (e.g., using pedicle screws or other posterior fixation devices) is strongly recommended.

Warning: When performing cauterization around an implant, avoid contact with the implant.

Postoperative

- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restriction and possible adverse reactions.

Revision surgery / Implant removal

The CONDUIT T/PLIF Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to correct the location, revise or remove the CONDUIT T/PLIF Cage, connect the Inserter or T-handle Inserter to the implant. When using the T-handle Inserter, turn 90 degree anti-clockwise to position the implant parallel in the intervertebral space. Slide the Hammer along the Inserter Shaft or T handle Inserter Shaft and relocate/remove the implant using gentle taps of the hammer. Or attach the Slap-hammer to the Slap-Hammer Knob of the Inserter/T-handle Inserter and relocate the implant with gentle slides of the Slap-Hammer.

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Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Note: For recognized legal manufacturer, refer to the product label.

EIT Emerging Implant Technologies GmbH
Eisenbahnstrasse 84
78573 Wurmlingen
Germany
Phone: +49 (0) 7461 171 69-00
Fax: +49 (0) 7461 171 69-09

For complaints reporting, please use the following contact details that are applicable:
Phone: +1-866-491-0974
Mail: depuyspineproductcomplaints@dpyus.jnj.com

www.depuysynthes.com

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CONDUIT™ Curved TLIF System

Surgical Technique

DePuy Synthes

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Indications and Contraindications

Indications

The CONDUIT TLIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT TLIF

Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

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Product Overview

CONDUIT™ Curved TLIF Implant

Lattice Structure Geometry

- ~ 80% porosity[1]
- ~ 700 µm diamond pore size[2]

Smooth introduction

Bullet banana shape and solid edges allow for a smooth introduction along soft tissues and adaptation to endplate anatomy

Rough surface

Rough elevated surface

Grafting

Designed to allow for bone grafting

Various sizes

Various footprint sizes for maximum endplate contact

- 10 x 28 mm
- 12 x 32 mm

Various heights

9 heights in 1 mm increments

- 7-15 mm

Several angles

0°, 8° and 12° lordosis angle for spinal alignment and sagittal balance

1. VAL2016-043 Strut diameter summary rev 0
2. EIT Scaffold characteristics P773 Signed Report_DM 20180417.

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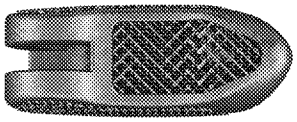
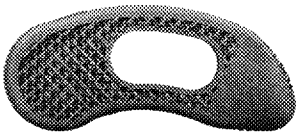
CONDUIT Curved TLIF Implants

10 mm x 28 mm (Width x Length)

	Lordosis		
Height	0°	8°	12°
7 mm	TUI00728		
8 mm	TUI00828	TUI80828	
9 mm	TUI00928	TUI80928	
10 mm	TUI01028	TUI81028	
11 mm	TUI01128	TUI81128	
12 mm	TUI01228	TUI81228	
13 mm	TUI01328	TUI81328	
14 mm		TUI81428	
15 mm	TUI01528	TUI81528	





12 mm x 32 mm (Width x Length)

	Lordosis		
Height	0°	8°	12°
7 mm			
8 mm	TUI00832	TUI80832	
9 mm	TUI00932	TUI80932	TUI30932
10 mm	TUI01032	TUI81032	TUI31032
11 mm	TUI01132	TUI81132	TUI31132
12 mm		TUI81232	TUI31232
13 mm	TUI01332	TUI81332	TUI31332
14 mm		TUI81432	TUI31432
15 mm	TUI01532	TUI81532	TUI31532

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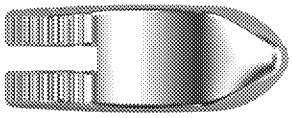
CONDUIT Curved TLIF Trials

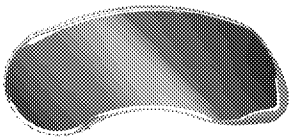
10 mm x 28 mm (Width x Length)

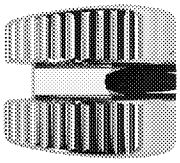
	Lordosis		
Height	0°	8°	12°
7 mm	TFT00728		
8 mm	TFT00828	TFT80828	
9 mm	TFT00928	TFT80928	
10 mm	TFT01028	TFT81028	
11 mm	TFT01128	TFT81128	
12 mm	TFT01228	TFT81228	
13 mm	TFT01328	TFT81328	
14 mm		TFT81428	
15 mm	TFT01528	TFT81528	



12 mm x 32 mm (Width x Length)

	Lordosis		
Height	0°	8°	12°
7 mm			
8 mm	TFT00832	TFT80832	
9 mm	TFT00932	TFT80932	TFT30932
10 mm	TFT01032	TFT81032	TFT31032
11 mm	TFT01132	TFT81132	TFT31132
12 mm	TFT01232	TFT81232	TFT31232
13 mm	TFT01332	TFT81332	TFT31332
14 mm		TFT81432	TFT31432
15 mm	TFT01532	TFT81532	TFT31532





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Shavers

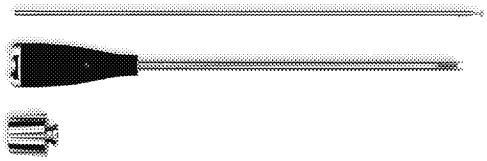
Height	Ref
7 mm	PFT10700
8 mm	PFT10800
9 mm	PFT10900
10 mm	PFT11000
11 mm	PFT11100
12 mm	PFT11200
13 mm	PFT11300
14 mm	PFT11400
15 mm	PFT11500

Distractors

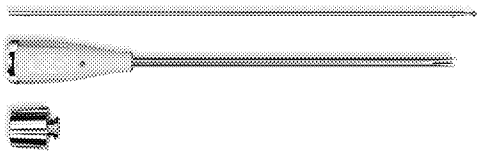
Height	Ref
7 mm	PET10710
8 mm	PET10810
9 mm	PET10910
10 mm	PET11010
11 mm	PET11110
12 mm	PET11210
13 mm	PET11310
14 mm	PET11410
15 mm	PET11510

PET10050 Disc Space Opener

TFT30101 Implant Inserter



TFT20101 Trial Inserter



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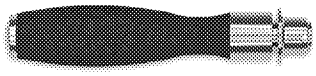
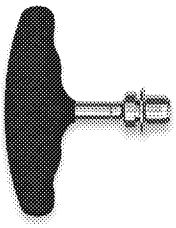
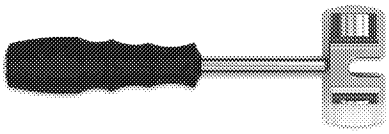
TET30201	Large Impactor	
PET00920	Straight handle	
PET00910	T-handle	
PET60251	Slap-Hammer	
PET60250	Hammer	
TEC00101	TLIF-C Instrument Tray Large	

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Imaging Characteristics

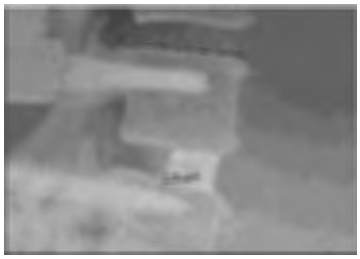
Imaging appearance* of the CONDUIT Curved TLIF cage

The CONDUIT TLIF Implant is visible in fluoroscopy and CT scans. The implant-endplate contact can be easily evaluated with no disturbing scattering on CT scans. The various lordosis angles and footprints in the CONDUIT portfolio allow for restoration of sagittal balance.

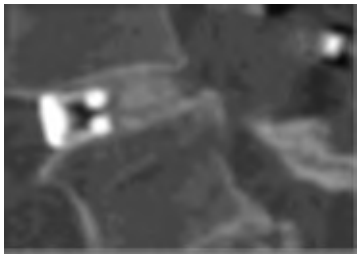
* Disclaimer: The CONDUIT implant images displayed on this page are of CONDUIT implants that are not FDA approved and not available in the USA.

X-Ray AP view. Curved TLIF implant used in conjunction with supplemental posterior pedicle screw fixation

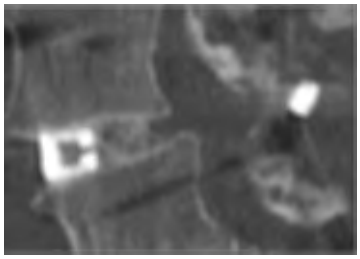
X-Ray lateral view showing lordosis restored to 17.4°. Curved TLIF implant used with supplemental posterior pedicle screw fixation



CT lateral view direct postoperative. L4-L5 and L5-S1 levels treated



CT lateral view 6 months postoperative. L4-L5 and L5-S1 levels treated



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Preparation and Approach

Position the patient in a restored physiological lordosis and decompress the abdomen to minimize venous stasis. Locate the correct operative level with fluoroscopic views. (Figure 1)

Discectomy

Make a standard incision, retract the muscle layer to view the desired segment. (Figure 2) Remove disc material through an incision in the annulus fibrosis. If desired, use the Disc Space Opener to access a severely collapsed disc. Shavers can be used to remove disc material and scrape the bony surface. (Figure 3) Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate preparation of the endplates without compromising the structural integrity is important to enable the access of an appropriate vascular supply to the bone graft to enable fusion.

Once the endplates have been prepared, complete additional surgical procedures.

Precautions:

- Injury to the bony endplates must be avoided as this may lead to implant subsidence.
- It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during implant insertion and interference with bone in-growth.
- Excessive removal of the subchondral bone may weaken the vertebral endplate. Removal of the entire endplate may result in subsidence and a loss of segmental stability.

Figure 1

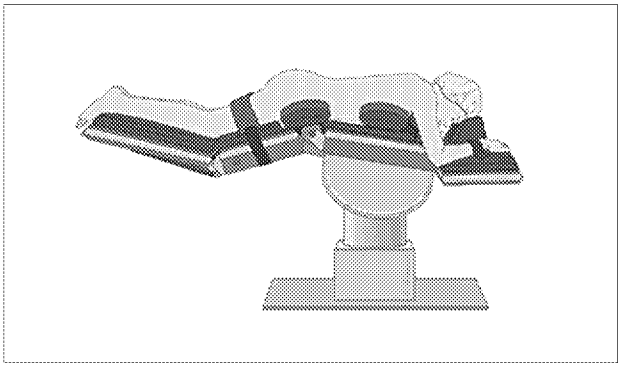


Figure 2

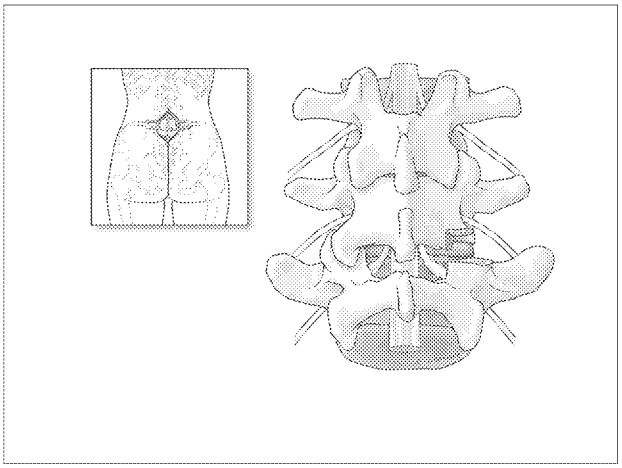
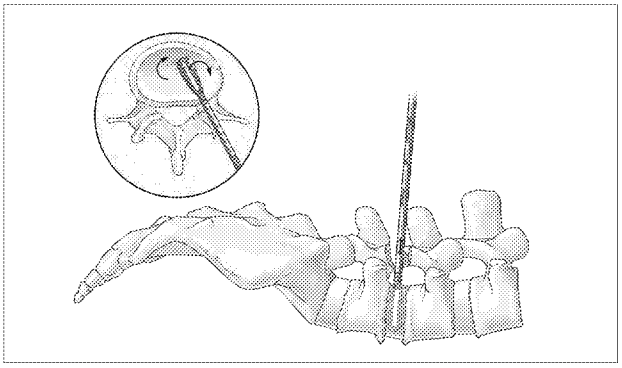


Figure 3



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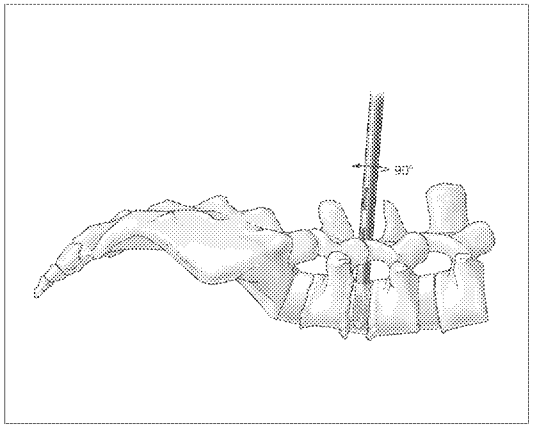
Distraction

Distraction opens the posterior disc space and promotes exposure both for decompression and delivery of the implant. Sufficient distraction should be applied to restore intervertebral height and provide stability of the implant. For this purpose, Distractors can be used. Distractors are available in heights of 7 mm to 15 mm in 1 mm increments. It is advised to start with the smallest size Distractor to avoid over distraction. Insert the Distractor parallel to the intervertebral space and carefully turn clockwise to open up the disc space to avoid injury of the endplates. Proceed with one size bigger until sufficient distraction is achieved. (Figure 4)

Figure 4



Precautions:

- **Use caution while using Distractors/Shavers to avoid damage to the endplate.**
- **Excessive removal of the subchondral bone may weaken the vertebral endplate. Removal of the entire endplate may result in subsidence and a loss of segmental stability.**

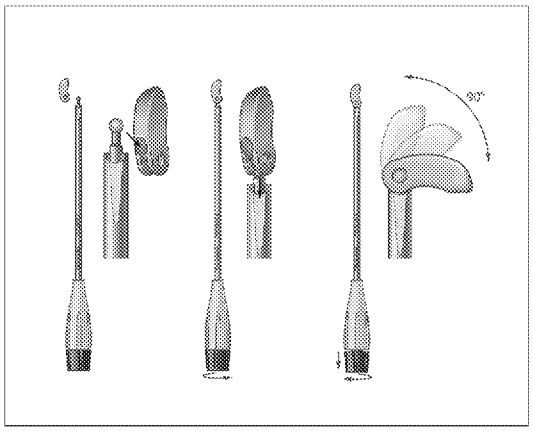
Trial - Inserter connection

Choose an appropriately sized Trial. Trials are available matching footprint, height, and angle of each implant.

Assembly Instructions Trial Inserter (Figure 5):

- Attach the knob to the Trial Inserter
- Next insert the Inner Pin. Make sure the Trial Inserter is properly assembled by inserting the Inner Pin with the spherical tip into the Trial Inserter Tube with the yellow handle. The components are engaged by tightening the knob on the back of the yellow handle.
- Position the spherical tip of the Trial Inserter into the Trial and attach the Trial to the Inserter by turning the knob on the back of the Inserter. The Trial can be positioned between 0° and 90° while engaged with the Trial Inserter by unscrewing the knob on the yellow handle. This allows for repositioning of the Trial without detachment from the Inserter.

Figure 5



Note: **Be careful not to use high forces on the Inserter when the knob is unscrewed more than two full turns as the screw thread could be damaged.**

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Trial for Implant Size

The longitudinal alignment of the Trial and Inserter ensures straight introduction of the Trial along the transforaminal route. Insert the Trial into the disc space, ensuring that the orientation of the Trial is correct. Controlled and light hammering on the Inserter may be required to advance the Trial into the intervertebral disc space. The tip should be positioned near the anterior edge of the adjacent vertebral bodies.
The position of the Inserter relative to the Trial can be changed by unlocking the knob and moving the Inserter medially. (Figure 6) Unthread the knob approximately a half turn and continue to impact the back of the Inserter until the desired position has been obtained.

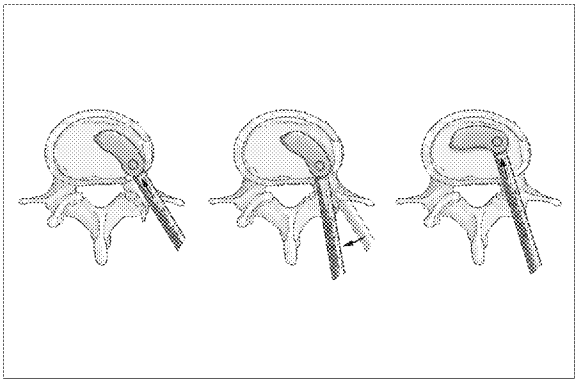
Use fluoroscopy during Trial insertion and to confirm final position and fit of the Trial.

Precautions:

- Do not leave the Trial in the disc space.
- Insufficient disc space preparation may compromise vascular supply to the bone graft.
- Be aware of soft tissue, blood vessels or neural elements that may be in the pathway of the Instruments or cause possible interference with retractor blades.
- Do not impact the Trial Inserter when the knob is unscrewed more than two full turns, as the screw thread could be damaged.

Note: If needed, the slotted Hammer can be used to remove the Trial.

Figure 6



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Implant - Inserter connection

Select the CONDUIT TLIF Implant that corresponds to the footprint, height and angle chosen using the Trial in the previous steps. To facilitate selection of the implant, the Trials are labeled with the height, lordotic angle and footprint of the implant.

Attach the knob to the Implant Inserter. Next insert the Inner Pin with the T-bar tip into the Inserter Tube with the black handle. The components are gripped by tightening the knob a few turns on the back of the handle.

- Open the sterile packaging of the implant that matches the selected Trial.
- Place the T-bar into the opening of the implant and turn the implant 90° (Figure 7). Align the tips of the Inserter with the notches on the medial and lateral sides of the implant. Turn the knob on the back on the Inserter until the implant is secured onto the Inserter.
- The implant must be packed with bone graft to facilitate the fusion process.

Note: The implant can be positioned between 0° and 90° while engaged with the Inserter by unscrewing the knob of the Inserter and changing the position of the Inserter-implant connection. (Figure 8)

After the CONDUIT TLIF cage is implanted, fill the posterior disc space and the lateral disc space with bone graft to create optimal conditions for fusion.

Figure 7

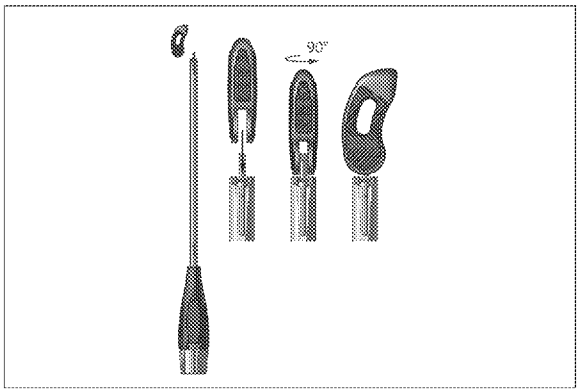
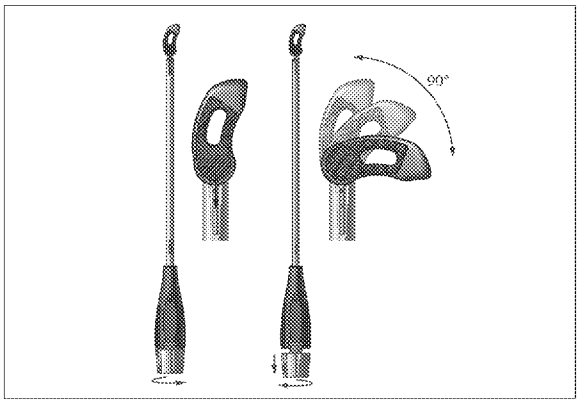


Figure 8



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Implant Insertion

The longitudinal alignment of the implant and Inserter ensures straight introduction of the implant along the transforaminal route. Recheck the firm connection of implant to Inserter. Insert the implant into the disc space, ensuring that the orientation of the implant is correct. Controlled and light hammering on the Inserter may be required to advance the implant into the intervertebral disc space. The position of the Inserter relative to the implant can be changed by unlocking the knob and moving the Inserter medially. Unthread the knob approximately a half turn and continue to impact the back of the Inserter until the desired position has been obtained. Use fluoroscopy during implant insertion and to confirm final position of the implant. (Figure 9)

Precautions:

- Be aware of soft tissue, blood vessels or neural elements that may be in the pathway of the implant as the porous structure may increase the risk of adherence.
- Do not impact the Inserter when the knob is unscrewed more than two full turns, as the screw thread could be damaged.

Final Implant Positioning

The implant should be positioned near the anterior edge of the adjacent vertebral bodies. Once proper placement is confirmed using flouroscopy, the inserter can be detached. Turn the inserter knob counter clockwise several rotations and pull gently on the inserter until the distal end of outer inserter shaft disengages from the slot on the implant . The cranial line on the outer shaft indicates the top of the T-Bar feature on the inner shaft (Figure 10). Using the cranial line as a reference, rotate the inserter 90° medially to align the T-bar with the implant slot (Figure 11), then pull gently on the inserter to release the implant (Figure 12).

If desired, an Impactor is available to position the implant after the Inserter has been removed. The Impactor can also be used to impact the remaining autograft into the intervertebral space.

Figure 9

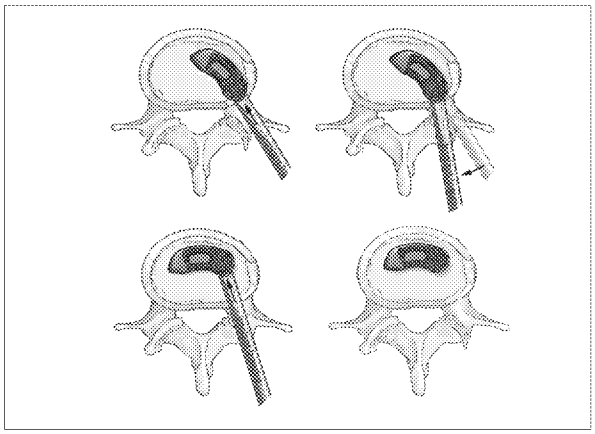


Figure 10

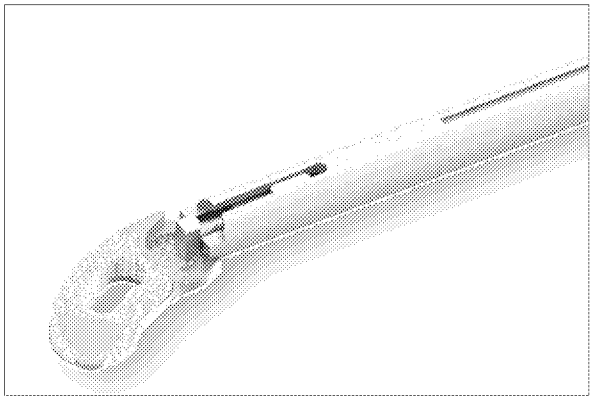


Figure 11

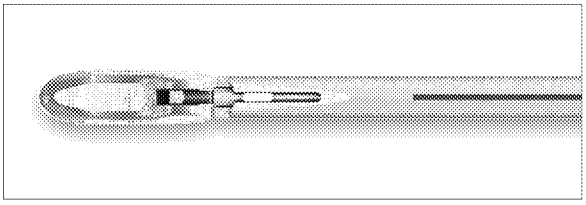
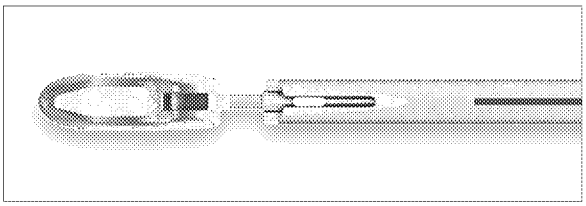


Figure 12



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Supplemental Fixation

The CONDUIT Curved TLIF Implant is intended to be used with supplemental fixation (e.g., pedicle screws or other posterior fixation devices).

Implant Removal / Revision Surgery

The CONDUIT TLIF Implant is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to adjust the position, revise or remove the CONDUIT Implant, connect the Inserter to the implant:

Option 1:
Use the slotted Hammer to facilitate removal of the implant. Slide the slotted Hammer along the Inserter Shaft and relocate /remove the implant using controlled light taps of the Hammer. (Figure 13)

Option 2:
Use the Slap Hammer to facilitate removal of the implant (Figure 14). Attach the Slap Hammer to the knob of the Inserter shaft and slide the Slap Hammer up and down to remove the implant.

Figure 13

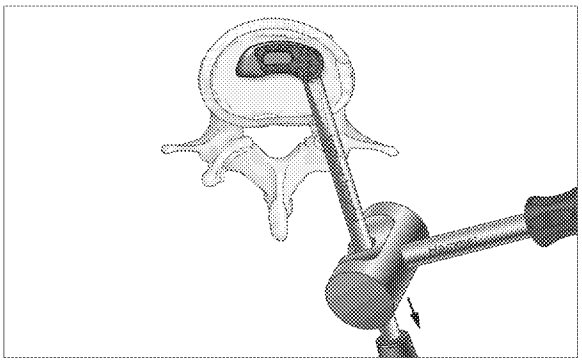

Figure 14

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Description

The CONDUIT TLIF Cage is an implant made from a titanium alloy for the posterior stabilization of the lumbar spinal column using a Transforaminal Lumbar Interbody Decompression and Fusion (TLIDF) surgery. CONDUIT TLIF Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

The 3D Printed CONDUIT TLIF Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Material

The CONDUIT TLIF Cage is made from titanium 6-aluminum 4-vanadium alloy (ASTM-F3001). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

Intended use / Indications

The CONDUIT TLIF Cages with a microscopic roughened surface and micro and nano-scale features, in combination with supplemental fixation, are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Contraindications

Do not use the CONDUIT TLIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thuspreclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device. Neurological difficulties include bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Each patient's record shall document the implant used (article number, description and lot number).

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- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use implants if the packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

Storage, inspection and resterilization

Storage
The implant is individually packed in protective packaging that is labeled according to its contents. The implant is sterilized with gamma sterilization (25 kGy minimum).
- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment)

Disinfection/cleaning
The implant is not designed to be disinfected or cleaned by the user.

Resterilization
The implant is not designed to be resterilized by the user.

Magnetic Resonance (MR) compatibility
Non-clinical testing has demonstrated that the CONDUIT TLIF Cage is MR Conditional and can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to 3,000 G/cm (30 T/m) for 1.5 T and 3T systems.
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 1.5 T and 3 T.

1.5 T and 3T RF heating
Under the scan conditions above, the CONDUIT TLIF Cage is expected to produce a maximum temperature rise of less than 0.5° C after 15 minutes of continuous scanning.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact
In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 2.1 cm from the device.

Procedure
Only implant the CONDUIT TLIF Cage with the applicable EIT TLIF instruments.
Note: The EIT TLIF instruments are available from the manufacturer at any time.

Preoperative
The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component(s) and their dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component(s)
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:
- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warnings:
Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.
- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight

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bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

Intraoperative
- Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.
- Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

Warnings:
Never use implants if the packaging is damaged.
Never use implants that are past their expiration date.

The CONDUIT TLIF Cage is inserted via the transforaminal approach, which is largely consistent with the principle of PLIF (Posterior Lumbar Interbody Fusion). Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.
- If necessary, use the Disc Space Opener to open up a severely collapsed disc.
- Perform a standard transforaminal lumbar decompression and discetomy. The (Endplate) Shaver may be used to remove disc material if necessary.
- Perform adequate distraction using the appropriate size (Parallel) Distractor. It should be considered to start with the smallest size Distractor to avoid over-distraction.
- Determine the appropriate implant size with the Trial situated on the Trial Inserter (SH Connection).
- Place the implant into position using the implant Inserter (SH Connection). If necessary, slightly adjust the location of the implant using the (Large) Impactor under X-ray control. Posterior supplemental internal fixation (e.g., using pedicle screws or other posterior fixation devices) is strongly recommended.

Warning: When performing cauterization around an implant, avoid contact with the Implant.

Postoperative
- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restriction and possible adverse reactions.

Revision surgery / Implant removal
The CONDUIT TLIF Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to correct the location, revise or remove the CONDUIT TLIF Cage, connect the Implant Inserter to the Implant. Slide the Hammer along the Implant Inserter Shaft and relocate/remove the implant using gentle taps of the Hammer. Or attach the Slap-Hammer Knob of the Trial Inserter/Implant Inserter and relocate the Trial/Implant with gentle slides of the Slap-Hammer.

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

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Note: For recognized legal manufacturer, refer to the product label.

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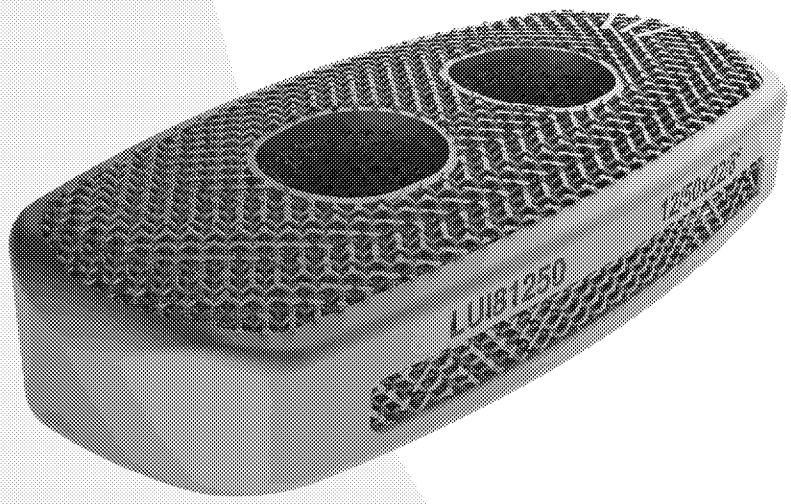
CONDUIT™ Lateral System

Surgical Technique



DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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Indications and Contraindications

Indications

The CONDUIT LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Contraindications

Do not use the CONDUIT LLIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stresses on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

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Product Overview

CONDUIT™ Lateral Lumbar Implants

Lattice Structure Geometry

- ~ 80% porosity[1]
- ~ 700 µm diamond pore size[2]

Rough surface

- Rough elevated surface

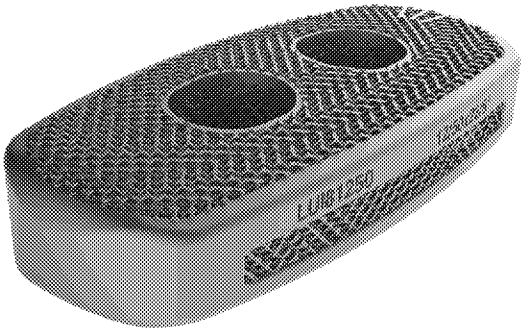
Grafting

- Designed to allow for bone grafting

Implant Portfolio

Wide variety of footprint sizes to allow the best fit for patient

- Widths: 18 mm, 22 mm, 26 mm
- Lengths: 40-60 mm length in 5 mm increments
- Lordotic angles: 0°, 8°, 16°
- Heights: 8-16 mm, in 2 mm increments depending on lordotic angle and width



1. VAL2016-043 Strut diameter summary rev 0.
2. EIT Scaffold characteristics P773 Signed Report_DM 20180417.

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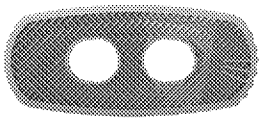
CONDUIT Lateral Lumbar Implants
18 mm, 0°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI00839	40	8	6.47	6.47
LUI01039	40	10	7.13	7.13
LUI01239	40	12	9.13	9.13
LUI01439	40	14	11.13	11.13
LUI01639	40	16	13.13	13.13
LUI00844	45	8	6.47	6.47
LUI01044	45	10	7.12	7.12
LUI01244	45	12	9.12	9.12
LUI01444	45	14	11.12	11.12
LUI01644	45	16	13.12	13.12
LUI00849	50	8	6.47	6.47
LUI01049	50	10	7.11	7.11
LUI01249	50	12	9.11	9.11
LUI01449	50	14	11.11	11.11
LUI01649	50	16	13.11	13.11
LUI00854	55	8	6.46	6.46
LUI01054	55	10	7.11	7.11
LUI01254	55	12	9.11	9.11
LUI01454	55	14	11.11	11.11
LUI01654	55	16	13.11	13.11
LUI00859	60	8	6.46	6.46
LUI01059	60	10	7.11	7.11
LUI01259	60	12	9.11	9.11
LUI01459	60	14	11.11	11.11
LUI01659	60	16	13.11	13.11



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CONDUIT Lateral Lumbar Implants continued

22 mm, 0°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI00840	40	8	6.44	6.44
LUI01040	40	10	7.09	7.09
LUI01240	40	12	9.09	9.09
LUI01440	40	14	11.09	11.09
LUI01640	40	16	13.09	13.09
LUI00845	45	8	6.43	6.43
LUI01045	45	10	7.08	7.08
LUI01245	45	12	9.08	9.08
LUI01445	45	14	11.08	11.08
LUI01645	45	16	13.08	13.08
LUI00850	50	8	6.43	6.43
LUI01050	50	10	7.08	7.08
LUI01250	50	12	9.08	9.08
LUI01450	50	14	11.08	11.08
LUI01650	50	16	13.08	13.08
LUI00855	55	8	6.43	6.43
LUI01055	55	10	7.07	7.07
LUI01255	55	12	9.07	9.07
LUI01455	55	14	11.07	11.07
LUI01655	55	16	13.07	13.07
LUI00860	60	8	6.43	6.43
LUI01060	60	10	7.07	7.07
LUI01260	60	12	9.07	9.07
LUI01460	60	14	11.07	11.07
LUI01660	60	16	13.07	13.07

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CONDUIT Lateral Lumbar Implants continued

26 mm, 0°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI00841	40	8	6.41	6.41
LUI01041	40	10	7.06	7.06
LUI01241	40	12	9.06	9.06
LUI01441	40	14	11.06	11.06
LUI01641	40	16	13.06	13.06
LUI00846	45	8	6.41	6.41
LUI01046	45	10	7.05	7.05
LUI01246	45	12	9.05	9.05
LUI01446	45	14	11.05	11.05
LUI01646	45	16	13.05	13.05
LUI00851	50	8	6.41	6.41
LUI01051	50	10	7.04	7.04
LUI01251	50	12	9.04	9.04
LUI01451	50	14	11.04	11.04
LUI01651	50	16	13.04	13.04
LUI00856	55	8	6.41	6.41
LUI01056	55	10	7.04	7.04
LUI01256	55	12	9.04	9.04
LUI01456	55	14	11.04	11.04
LUI01656	55	16	13.04	13.04
LUI00861	60	8	6.41	6.41
LUI01061	60	10	7.04	7.04
LUI01261	60	12	9.04	9.04
LUI01461	60	14	11.04	11.04
LUI01661	60	16	13.04	13.04

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CONDUIT Lateral Lumbar Implants continued

18 mm, 8°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI80839	40	8	7.38	5.01
LUI81039	40	10	8.21	5.77
LUI81239	40	12	10.21	7.77
LUI81439	40	14	12.21	9.77
LUI81639	40	16	14.21	11.77
LUI80844	45	8	7.38	5.01
LUI81044	45	10	8.2	5.76
LUI81244	45	12	10.2	7.76
LUI81444	45	14	12.2	9.76
LUI81644	45	16	14.2	11.76
LUI80849	50	8	7.38	5.01
LUI81049	50	10	8.2	5.76
LUI81249	50	12	10.2	7.76
LUI81449	50	14	12.2	9.76
LUI81649	50	16	14.2	11.76
LUI80854	55	8	7.38	5.01
LUI81054	55	10	8.19	5.75
LUI81254	55	12	10.19	7.75
LUI81454	55	14	12.19	9.75
LUI81654	55	16	14.19	11.75
LUI80859	60	8	7.38	5.01
LUI81059	60	10	8.19	5.75
LUI81259	60	12	10.19	7.75
LUI81459	60	14	12.19	9.75
LUI81659	60	16	14.19	11.75

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CONDUIT Lateral Lumbar Implants continued

22 mm, 8°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI80840	40	8	7.49	4.58
LUI81040	40	10	8.37	5.4
LUI81240	40	12	10.37	7.4
LUI81440	40	14	12.37	9.4
LUI81640	40	16	14.37	11.4
LUI80845	45	8	7.49	4.58
LUI81045	45	10	8.37	5.39
LUI81245	45	12	10.37	7.39
LUI81445	45	14	12.37	9.39
LUI81645	45	16	14.37	11.39
LUI80850	50	8	7.49	4.57
LUI81050	50	10	8.36	5.39
LUI81250	50	12	10.36	7.39
LUI81450	50	14	12.36	9.39
LUI81650	50	16	14.36	11.39
LUI80855	55	8	7.49	4.57
LUI81055	55	10	8.36	5.38
LUI81255	55	12	10.36	7.38
LUI81455	55	14	12.36	9.38
LUI81655	55	16	14.36	11.38
LUI80860	60	8	7.49	4.57
LUI81060	60	10	8.36	5.38
LUI81260	60	12	10.36	7.38
LUI81460	60	14	12.36	9.38
LUI81660	60	16	14.36	11.38

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CONDUIT Lateral Lumbar Implants continued

26 mm, 8°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI80841	40	8	7.59	4.12
LUI81041	40	10	8.54	5.02
LUI81241	40	12	10.54	7.02
LUI81441	40	14	12.54	9.02
LUI81641	40	16	14.54	11.02
LUI80846	45	8	7.59	4.12
LUI81046	45	10	8.53	5.01
LUI81246	45	12	10.53	7.01
LUI81446	45	14	12.53	9.01
LUI81646	45	16	14.53	11.01
LUI80851	50	8	7.59	4.12
LUI81051	50	10	8.52	5.01
LUI81251	50	12	10.52	7.01
LUI81451	50	14	12.52	9.01
LUI81651	50	16	14.52	11.01
LUI80856	55	8	7.59	4.12
LUI81056	55	10	8.52	5
LUI81256	55	12	10.52	7
LUI81456	55	14	12.52	9
LUI81656	55	16	14.52	11
LUI80861	60	8	7.58	4.12
LUI81061	60	10	8.52	5
LUI81261	60	12	10.52	7
LUI81461	60	14	12.52	9
LUI81661	60	16	14.52	11

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CONDUIT Lateral Lumbar Implants continued
18 mm, 16°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI71039	40	10	9.75	4.99
LUI71239	40	12	11.02	6.13
LUI71439	40	14	13.02	8.13
LUI71639	40	16	15.02	10.13
LUI71044	45	10	9.75	4.99
LUI71244	45	12	11.02	6.12
LUI71444	45	14	13.02	8.12
LUI71644	45	16	15.02	10.12
LUI71049	50	10	9.75	4.99
LUI71249	50	12	11.01	6.11
LUI71449	50	14	13.01	8.11
LUI71649	50	16	15.01	10.11
LUI71054	55	10	9.75	4.99
LUI71254	55	12	11.01	6.11
LUI71454	55	14	13.01	8.11
LUI71654	55	16	15.01	10.11
LUI71059	60	10	9.75	4.99
LUI71259	60	12	11	6.11
LUI71459	60	14	13	8.11
LUI71659	60	16	15	10.11

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CONDUIT Lateral Lumbar Implants continued

22 mm, 16°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI71040	40	10	9.74	3.88
LUI71240	40	12	11.26	5.29
LUI71440	40	14	13.26	7.29
LUI71640	40	16	15.26	9.29
LUI71045	45	10	9.74	3.88
LUI71245	45	12	11.25	5.28
LUI71445	45	14	13.25	7.28
LUI71645	45	16	15.25	9.28
LUI71050	50	10	9.74	3.88
LUI71250	50	12	11.25	5.27
LUI71450	50	14	13.25	7.27
LUI71650	50	16	15.25	9.27
LUI71055	55	10	9.74	3.38
LUI71255	55	12	11.24	5.27
LUI71455	55	14	13.24	7.27
LUI71655	55	16	15.24	9.27
LUI71060	60	10	9.74	3.38
LUI71260	60	12	11.24	5.27
LUI71460	60	14	13.24	7.27
LUI71660	60	16	15.24	9.27

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CONDUIT Lateral Lumbar Implants continued

26 mm, 16°

	Length (mm)	Height (mm)	Anterior Height (mm)	Posterior Height (mm)
LUI71241	40	12	11.46	4.4
LUI71441	40	14	13.46	6.4
LUI71641	40	16	15.46	8.4
LUI71246	45	12	11.45	4.39
LUI71446	45	14	13.45	6.39
LUI71646	45	16	15.45	8.39
LUI71251	50	12	11.45	4.38
LUI71451	50	14	13.45	6.38
LUI71651	50	16	15.45	8.38
LUI71256	55	12	11.44	4.38
LUI71456	55	14	13.44	6.38
LUI71656	55	16	15.44	8.38
LUI71261	60	12	11.44	4.37
LUI71461	60	14	13.44	6.37
LUI71661	60	16	15.44	8.37

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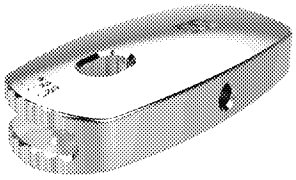
CONDUIT Lateral Lumbar Trials

22 mm, 0°

	Angle (Deg)	Width (mm)	Length (mm)	Height (mm)
LET00840	0	22	40	8
LET01040	0	22	40	10
LET01240	0	22	40	12
LET01440	0	22	40	14
LET01640	0	22	40	16
LET00845	0	22	45	8
LET01045	0	22	45	10
LET01245	0	22	45	12
LET01445	0	22	45	14
LET01645	0	22	45	16
LET00850	0	22	50	8
LET01050	0	22	50	10
LET01250	0	22	50	12
LET01450	0	22	50	14
LET01650	0	22	50	16
LET00855	0	22	55	8
LET01055	0	22	55	10
LET01255	0	22	55	12
LET01455	0	22	55	14
LET01655	0	22	55	16
LET00860	0	22	60	8
LET01060	0	22	60	10
LET01260	0	22	60	12
LET01460	0	22	60	14
LET01660	0	22	60	16



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CONDUIT Lateral Lumbar Trials continued

22 mm, 8°

	Angle (Deg)	Width (mm)	Length (mm)	Height (mm)
LET80840	8	22	40	8
LET81040	8	22	40	10
LET81240	8	22	40	12
LET81440	8	22	40	14
LET81640	8	22	40	16
LET80845	8	22	45	8
LET81045	8	22	45	10
LET81245	8	22	45	12
LET81445	8	22	45	14
LET81645	8	22	45	16
LET80850	8	22	50	8
LET81050	8	22	50	10
LET81250	8	22	50	12
LET81450	8	22	50	14
LET81650	8	22	50	16
LET80855	8	22	55	8
LET81055	8	22	55	10
LET81255	8	22	55	12
LET81455	8	22	55	14
LET81655	8	22	55	16
LET80860	8	22	60	8
LET81060	8	22	60	10
LET81260	8	22	60	12
LET81460	8	22	60	14
LET81660	8	22	60	16

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CONDUIT Lateral Lumbar Trials continued

22 mm, 16°

	Angle (Deg)	Width (mm)	Length (mm)	Height (mm)
LET71040	16	22	40	10
LET71240	16	22	40	12
LET71440	16	22	40	14
LET71640	16	22	40	16
LET71045	16	22	45	10
LET71245	16	22	45	12
LET71445	16	22	45	14
LET71645	16	22	45	16
LET71050	16	22	50	10
LET71250	16	22	50	12
LET71450	16	22	50	14
LET71650	16	22	50	16
LET71055	16	22	55	10
LET71255	16	22	55	12
LET71455	16	22	55	14
LET71655	16	22	55	16
LET71060	16	22	60	10
LET71260	16	22	60	12
LET71460	16	22	60	14
LET71660	16	22	60	16

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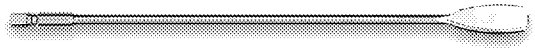
Shaver

Height	Ref
8 mm	LET10800
10 mm	LET11000
12 mm	LET11200
14 mm	LET11400
16 mm	LET11600

Distractor

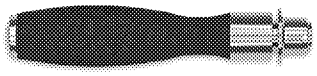
Height	Ref
8 mm	AET10208
10 mm	AET10210
12 mm	AET10212
14 mm	AET10214
16 mm	AET10216



LET10101	Cobb elevator small

LET10100	Cobb elevator large

PET00920	Straight handle



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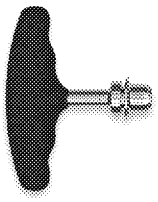
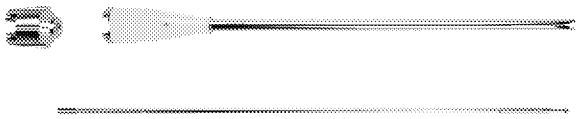
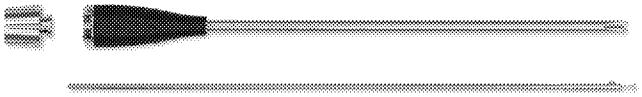
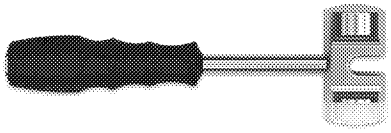
PET00910	T-handle	
LET20100	Trial Inserter	
LET30100	Implant Inserter	
PET60250	Hammer	
PET60251	Slap hammer	
LET30200	Implant Pusher	
LEC00101	LLIF General Instrument Tray	

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Preparation and Positioning

A lateral approach will be used to access the spine and perform a lateral interbody fusion. Adequate consideration should be given to patient positioning. A radiolucent OR table is recommended as fluoroscopy should be used to identify the affected disc and, in a later stage, evaluate implant positioning.

Position the patient on the OR table in the lateral decubitus position. The patient can be placed on a bendable surgical table so that the table break is located between the top of the iliac crest and greater trochanter. Flexion of the table can be used to aid in the opening of the space between the lowest rib and the iliac crest. For an 'anterior to the psoas' approach, the table should be tilted 30°. Once the desired position is achieved, secure the patient (Figures 1 & 2). If intra-operative neuromonitoring is used, apply all desired electrodes or patches prior to positioning the patient.

The CONDUIT LLIF Implant is designed to be used in a trans psoas approach as well as an anterior to psoas approach.

Figure 1

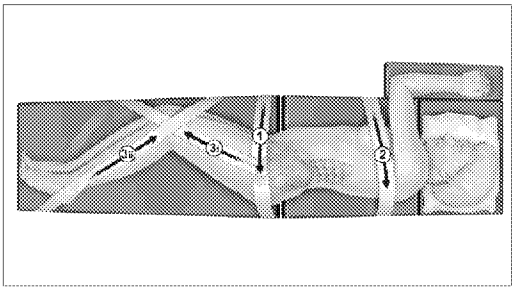
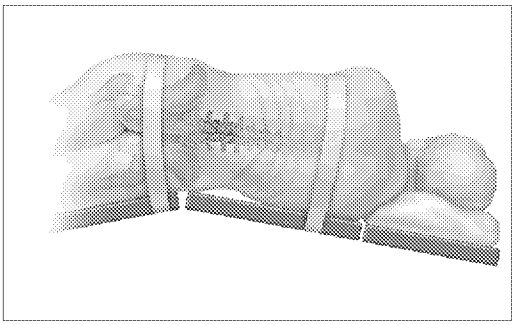


Figure 2



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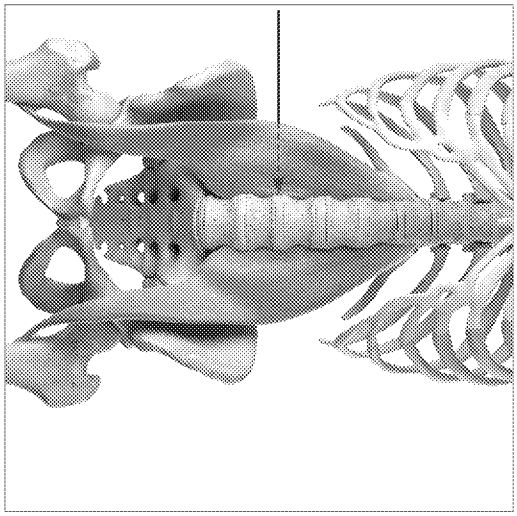
Approach: Trans Psoas

Once patient is positioned, adjust table to ensure true anterior-posterior (AP) and lateral fluoroscopic images of the affected levels. Once disc space is identified using fluoroscopy, draw target lines in the operational area. A transverse incision is made over the target level and the abdominal muscle layers should be dissected blunt in the line of the muscle fibers. Bluntly penetrate the transversalis fascia exposing the retroperitoneal fat. Once inside the retroperitoneal space, palpation or visualization of the psoas muscle is necessary prior to insertion of the dilators and subsequently the retractor, within the psoas muscle (Figure 3).

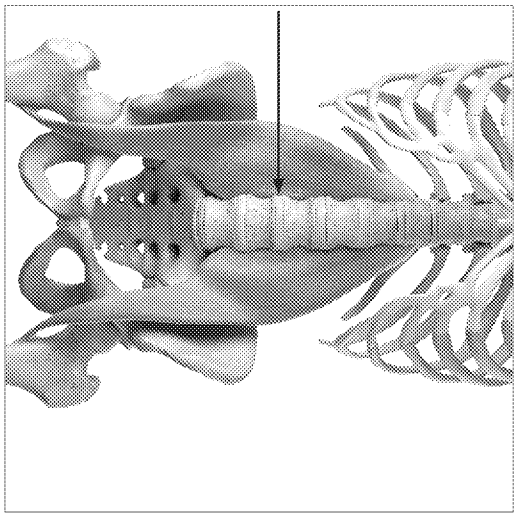
Figure 3



Approach: Anterior to Psoas

After placing the patient in a stable position and tilting the OR table 30°, check true lateral and anterior-posterior (AP) images using fluoroscopy. A transverse incision parallel to the external oblique muscle is made 2 finger breadths anterior to the iliac crest. The abdominal muscle layers should be dissected blunt in the line of the muscle fibers. Bluntly penetrate the transversalis fascia exposing the retroperitoneal fat. Once inside the retroperitoneal space, palpation or visualization of the psoas muscle is necessary. Once on the psoas muscle, follow it antero-medially and then backwards to the spine. The anterior longitudinal ligament serves as a medial landmark and the border of the psoas muscle is identified as a lateral landmark and retracted on the disc space level (Figure 4). Use appropriate retraction to push the psoas muscle posteriorly.

Figure 4



Precaution: With the retroperitoneal approach, ensure no loop of bowel is present in the approach corridor.

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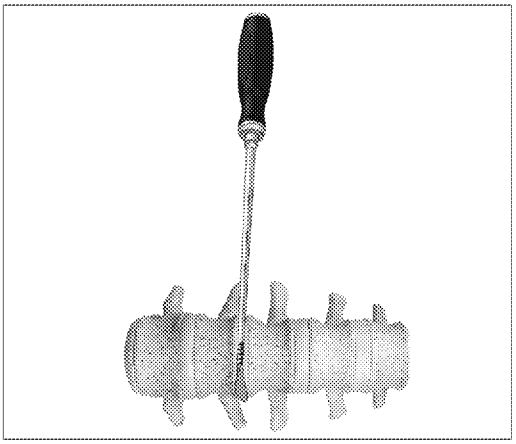
Discectomy

Once appropriate access to the disc space has been established and no neurovascular structures are present, an annulotomy can be made with an annulotomy knife. The annulotomy should be at least as long as the width of the implant. Under fluoroscopy, carefully pass the Cobb elevator along both endplates completely through to the contralateral annulus. Use a straight Cobb elevator to disrupt the disc from both vertebral endplates and release the contralateral annulus (Figure 5). This will allow for the implant to sit on the contralateral apophyseal ring.

Figure 5



Using pituitaries, curettes, box cutters, rasps or other long disc preparation instruments, remove disc material and clean the endplates. After the disc is cleaned thoroughly, the endplate cartilage should be removed carefully, leaving the upper and lower bony endplates intact.

Note: Care should be taken to ensure all instruments are used in a fashion parallel to the endplate, which can be checked under AP fluoroscopy.

Paddle Distractors and Shavers are available in heights of 8 mm to 16 mm in 2 mm increments for further distraction and cleaning of the disc space.

Precautions:

- It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during implant insertion and interference with bone in growth.
- Overly aggressive preparation can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to the loss of segmental stability.
- To prevent damage to soft tissue or vascular structures use the Cobb elevator in a controlled fashion and under fluoroscopy when crossing the disc space to release the contralateral annulus.

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Trial - Inserter Connection

Choose an appropriately sized footprint trial. Trials are available matching footprint, height, and angle of each implant.

Assembly Instructions:
1. Insert knob at top of handle
2. Insert inner shaft into Trial Inserter handle, centrally align until flush with Trial Inserter handle, and tighten knob clockwise until thicker portion of inner shaft is flush with distal tip of Trial Inserter (Figure 6)
3. Slide spherical tip into the trial, tighten by turning knob clockwise (Figure 7)

Notes:
- The trial can be positioned at three angles, 0°, 12°, 24°. The 0° connection is used for the direct lateral approach and the 12° and 24° is used for the anterior to psoas approach.
- Implants are slightly higher (0.25mm) than the trials due to the implant's porous structure.

Precaution: Ensure that all disc material is removed to prevent displacement of disc material into the spinal canal during trial insertion.

Figure 6

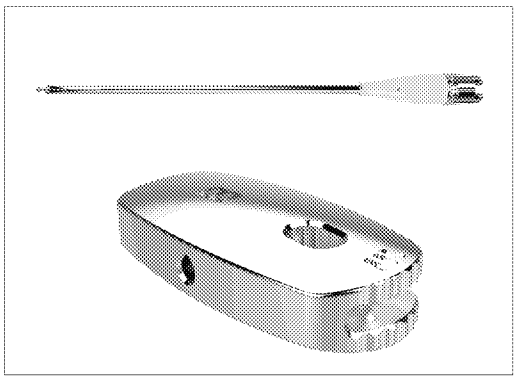
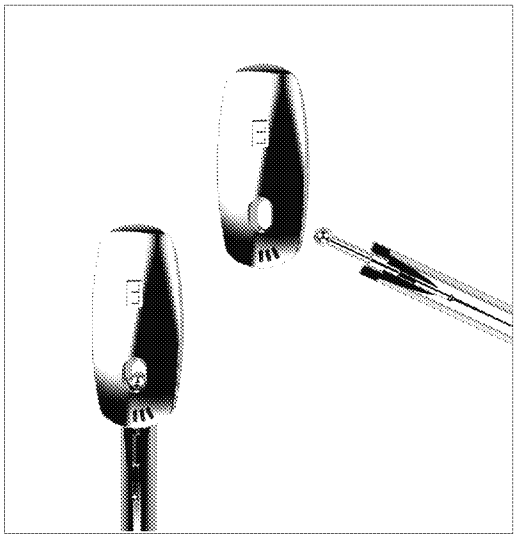


Figure 7



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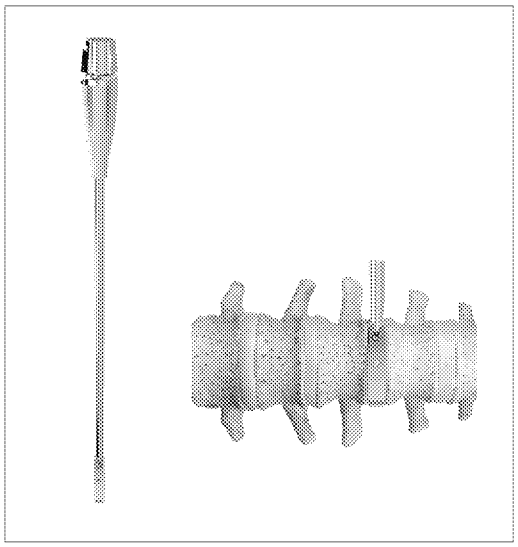
Trial for Implant Size

Use trials to determine the correct implant size. Every trial has a machined number indicating the lordotic angle. Start with the smallest appropriate sized initial trial and increase as needed. Fluoroscopy should be used to confirm a secure fit, optimal dimensions, and final position of the trial (Figure 8). The trial has a central hole, which allows correct evaluation of the position in AP fluoroscopy image.

Figure 8



Implant - Inserter connection

Open the sterile packaging of the implant size that was determined with the trial.
Attach the implant to the Implant Inserter:

1. Insert knob at top of handle
2. Insert inner shaft into Implant Inserter handle, centrally align the key into the slot until flush with Implant Inserter handle and tighten knob clockwise until thicker portion of inner shaft is flush with distal tip of Implant Inserter (Figure 9).
3. Place T-bar in opening, turn 90° and tighten clockwise (Figure 10).

Note: The implant can be positioned on the Implant Inserter at three angles, 0°, 12°, 24°. The 0° connection is used for the trans psoas approach and the 12° and 24° is used for the anterior to psoas approach.

Figure 9

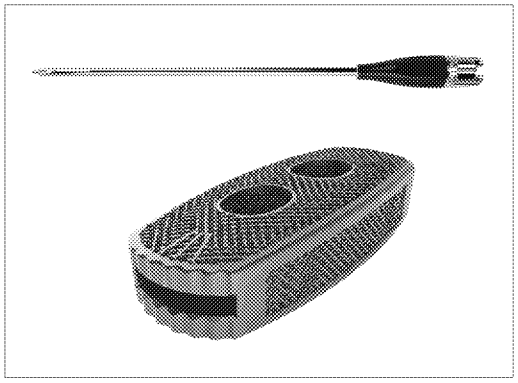
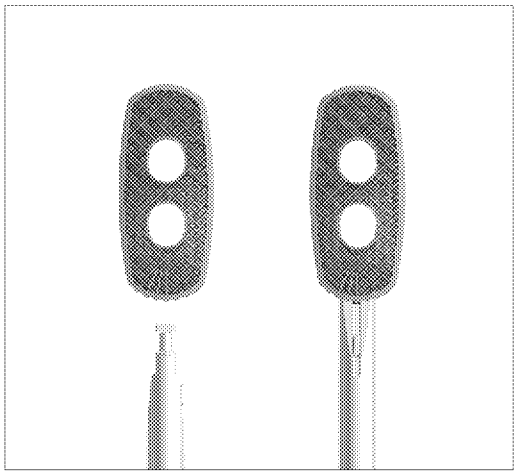


Figure 10



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Implant Insertion

The implant is introduced in the same way as the trial. Again, verify position using fluoroscopy. The use of fluoroscopy is recommended during all implantation steps to ensure proper positioning.

The implant should cover the endplate as much as possible and match the endplate concavity (Figure 11). Once proper placement is confirmed using fluoroscopy proceed with the following steps:

1. Turn knob at end of shaft counter clockwise, (approximately ~7 rotations)
2. Then, turn Implant Inserter 90° and detach from implant, pull Implant Inserter gently backwards, detaching the T- bar connection from the implant (Figure 12)

Flatten table and use fluoroscopy to determine final positioning of implant.

Warning: If the implant has been inserted past the epiphyseal ring, it may be more difficult to adjust or remove and additional distraction may be required.

Figure 11

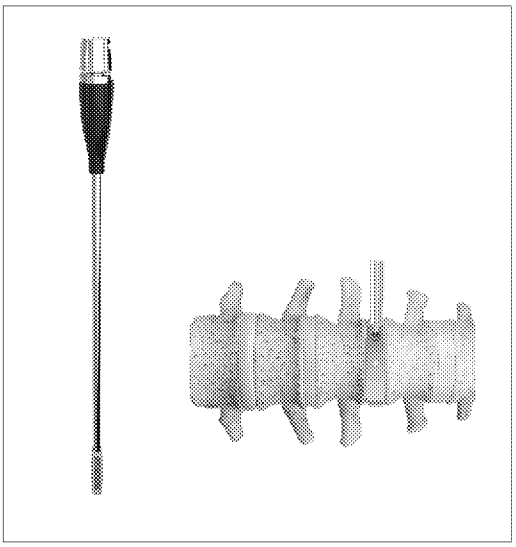
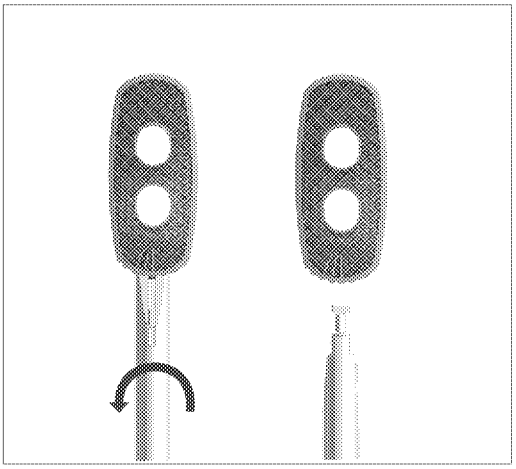


Figure 12



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Supplemental Fixation

The CONDUIT LLIF Implant is intended to be used with supplemental fixation (e.g., lateral plating, pedicle screws, or other posterior fixation devices).

Implant Removal / Revision

The CONDUIT LLIF Implant is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

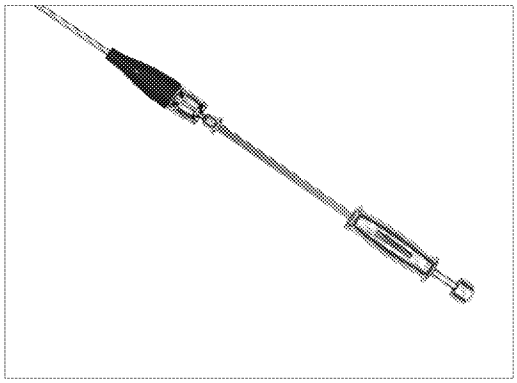
If it is necessary to adjust the position, revise or remove the CONDUIT LLIF Implant, connect the Implant Inserter to the implant:

Option 1:
Use the slotted Hammer to facilitate removal of implant.

Option 2:
Use the Slap hammer to facilitate removal of implant (Figure 13). Attach Slap hammer to knob of the Implant Inserter shaft and slide Slap hammer up and down to remove implant.

Warning: The implant may be difficult to remove due to the surface roughness and the position of the cage. If the implant has been inserted past the epiphyseal ring, it may be more difficult to remove and additional distraction may be required.

Figure 13



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Instructions for Use

Description

The CONDUIT LLIF Cage is an implant made from a titanium alloy for the lateral stabilization of the lumbar spinal column using a Lateral Lumbar Interbody Decompression and Fusion (LLIDF) surgery. CONDUIT LLIF Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

The 3D Printed CONDUIT LLIF Cage has a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

Material

The CONDUIT LLIF Cage is made from titanium 6-aluminum 4-vanadium alloy (ASTM-F3001). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

Intended use / Indications

The CONDUIT LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of
cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least
six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Contraindications

Do not use the CONDUIT LLIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device. Neurological difficulties include bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions.
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Each patient's record shall document the implant used (article number, description and lot number).

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- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use an implant if its packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

Storage, inspection and resterilization

Storage
The implant is individually packed in protective packaging that is labeled according to its content. The implant is sterilized with gamma sterilization (25 kGy minimum).
- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment).

Disinfection/cleaning
The implant is not designed to be disinfected or cleaned by the user.

Resterilization
The implant is not designed to be resterilized by the user.

Magnetic Resonance (MR) compatibility
Non-clinical testing has demonstrated that the CONDUIT LLIF Cage is MR Conditional and can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to 4,000 gauss / cm (40 T/m)
- Maximum MR system report, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

1.5 T RF heating
In non-clinical testing with body coil excitation, the CONDUIT Cage produced a temperature rise of less than 3.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 T Philips Intera MR scanner with Software Release 12.6.1.4, 2012-05-22.

3 T RF heating
In non-clinical testing, the CONDUIT Cage produced a temperature rise of 2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 T Siemens Magnetom Trio MR scanner with Numaris/4, Syngo MR B17 software.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact
In testing with spin-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 29.5 mm from the device.

Procedure
Only implant the CONDUIT LLIF Cage with the applicable EIT LLIF instruments.
Note: The EIT LLIF instruments are available from the manufacturer at any time.

Preoperative
The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component and the dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:
- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warning: Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

Warning: The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.

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- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:

- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

Intraoperative

- Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.
- Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

Warning: Never use the implants if the packaging is damaged.

Warning: Never use implants that are past their expiration date.

The CONDUIT LLIF Cage is inserted via the lateral approach. Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.

- If necessary, use the Disc Space Opener to open up a severely collapsed disc.
- Perform a standard lateral lumbar decompression and discectomy. The (Endplate) Shaver may be used to remove disc material if necessary.
- Perform adequate distraction using the appropriate size (Parallel) Distractor. It should be considered to start with the smallest size Distractor to avoid over-distraction.
- Determine the appropriate implant size with the Trial situated on the Trial Inserter (SH Connection).
- Place the implant into position using the Implant Inserter (SH Connection). If necessary, slightly adjust the location of the implant using the Implant Pusher under X-ray control. Lateral and/or posterior supplemental internal fixation (e.g., using pedicle screws or other posterior fixation devices) is strongly recommended.

Lateral and/or posterior supplemental internal fixation (e.g., using pedicle screws or other posterior fixation devices) is strongly recommended.

Warning: When performing cauterization around an implant, avoid contact with the implant.

Postoperative

- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

Revision surgery / Implant removal

The CONDUIT LLIF Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

If it is necessary to correct the location, revise or remove the CONDUIT LLIF Cage, connect the Implant Inserter to the implant. Slide the Hammer along the Implant Inserter Shaft and relocate/remove the implant using gentle taps of the Hammer. Or attach the Slap-Hammer Knob of the Trial Inserter/ Implant Inserter and relocate the Trial/Implant with gentle slides of the Slap-Hammer.

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

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Phone: +49 (0) 7461 171 69-00
Fax: +49 (0) 7461 171 69-09

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10354237/0 Rev 4 [illegible]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Prosidyan

Certificate of Conformance

No. 20220301-04

This document certifies that the parts listed below comply with the specifications, drawings, and all other requirements of Prosidyan, Inc. All required inspection(s) and test(s) have been performed and completed successfully. Test and inspection results for the parts certified within, are on file at Prosidyan, Inc., New Providence, NJ.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Justin,

Thanks for this additional piece of information. We appreciate it.

Have a great rest of your week,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Monday, October 10, 2022 8:47 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thanks,

Justin

[cid:image002.png@01D8DEEA.49F20160]<http://secure-web.cisco.com/1yv7FGwt-dcUKPgYtMNi8uLqSahY3ek6HJ08jrypWfXNusyCVXkZc4JXMH1j1u8GEDt2P9UmY8NiFNNt9mCgdCzRI1lGPbPz_06ECCDPHuIhoN8A1ahccgl_ZIpbI2smN3QZcisl3f32_MHfHy6NLpoOdVHM2432FUo7AAGY5bEuExBavYTWvhFzD87vsk7ZZpogUp8MnscsDf9Vbro4WGw/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1yv7FGwt-dcUKPgYtMNi8uLqSahY3ek6HJ08jrypWfXNusyCVXkZc4JXMH1j1u8GEDt2P9UmY8NiFNNt9mCgdCzRI1lGPbPz_06ECCDPHuIhoN8A1ahccgl_ZIpbI2smN3QZcisl3f32_MHfHy6NLpoOdVHM2432FUo7AAGY5bEuExBavYTWvhFzD87vsk7ZZpogUp8MnscsDf9Vbro4WGw/http%3A%2F%2Fwww.mcra.com%2F>

[cid:image004.jpg@01D8DEEA.49F20160]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<http://secure-web.cisco.com/1VnBULoz-YtQfJLPockl8ERjsoNfmkP-FVXu2qbiq4AsHj55hvolTHP9tzrGalLdbPtEmsu7DBeG0Nhu9VpLi28mTR5R1rRTVED4B8te2gq5t1TtrfDskUkFz-YmakcLR-g3zI9Sx0Xh2qN44-vBf-ar07CyZSc4864hqA-Y_3-oHukDE7f01crlUnXA0levlrE_BTufiiD1Vkj6FMDBGRQ/http%3A%2F%2Fwww.eventleaf.com%2Fe%2FNASSnetworking>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Friday, October 07, 2022 9:21 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Thursday, October 6, 2022 7:05 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,

Justin

[cid:image005.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456800863679%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=KaNOHGOLm4cFPCuxG7U8Y%2BRe35pYAFVWJirRZw2ixV4%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1ceZn9tmBYRqm51ELCcrZyyyoK5FrwYHV8ODIgPvcHd8tQb4s_0EG8KKyrdNljPFuOgjbD5w4LKwZr5XmGXFIV3wAM8YGWMxCpvNxaVyPLi8RNvfy1ip25_UR6cN8pNLAuZ_fL7OZOO8yswmJWMFSwj1fj6EYSPdMYblGYoYUChWZxwy2aSIl4Wma-PP9EhHeONbp4wYDyjzRJ9Pj8hFPig%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=%2FSPPcfzCHRF18%2Fn2zvXRAi85%2Fz6vE2C3Jn6%2FJ3sF2ds%3D&reserved=0>

[cid:image004.jpg@01D8DEEA.49F20160]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Thursday, October 06, 2022 4:24 PM

To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,

Jennifer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

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Justin

[cid:image006.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=VozLhNvyvz0Sehy7epRLZGDuaiFnZ53PTUieOnPOXJU%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801019901%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=VozLhNvyvz0Sehy7epRLZGDuaiFnZ53PTUieOnPOXJU%3D&reserved=0>

[cid:image004.jpg@01D8DEEA.49F20160]

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=rSQ7J0D9yiGNdT%2FOSjfyZF%2BINRckne27XVJ8ZSE5wmg%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image008.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=vlGSgszliBw8mF%2Bt57WWeZaI%2Fc8rqXgmnPNdDHPbziI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=vlGSgszliBw8mF%2Bt57WWeZaI%2Fc8rqXgmnPNdDHPbziI%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend (b)(4) (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Justin

[cid:image008.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801176131%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=mXzcVr2PAGNsgi9K0QhrsH6Y%2B5SQSPB5UJWGNvwPFAY%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801336708%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Vpd%2F0l75GZzaIsxHdJcNk2itRPerUAsByJmRktaHZsg%3D&reserved=0>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image012.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801346643%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=GxD%2Fa3NWZnJEB2P58%2FKGPqJ31ONoeZNH0Pa8LciLsw0%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801346643%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=GxD%2Fa3NWZnJEB2P58%2FKGPqJ31ONoeZNH0Pa8LciLsw0%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image021.png@01D8DEEA.49F20160]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638007456801346643%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=fzHIg%2BsSQgVlL1gVWOYX0lh%2BdMPFdun%2Bknrl5xDCrmk%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.flickr.com%2Fphot
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[cid:image027.jpg@01D8DEEA.49F20160]
<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFD
A%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.
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D&reserved=0>

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https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E<https://nam10.safelinks.prot
ection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7C03ed968d6a454c0659b008daa866cc14%7C
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

These devices do not include an electrical component. This section is therefore not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

Records processed under FOIA Request 2023-4334; Released by CDRH on 10-15-2024

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

Hi Justin,

Thank you very much! Your response addresses all our questions. We'll be in touch during our substantive review if we have other information requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, August 10, 2022 9:29 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - Clarifying question

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Jennifer,

(b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Monday, August 08, 2022 12:23 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - Clarifying question

Hello Justin,

I have one minor question in addition to my recently issued request for information. (b)(6)

(b)(4)

Thank you,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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Good morning Justin,

Thanks for the reply and update. I'll look forward to receiving your response later today.

Thanks,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Thursday, October 6, 2022 7:05 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Thursday, October 06, 2022 4:24 PM
To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,
Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Sent: Wednesday, October 5, 2022 5:58 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,
That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.
Phil

From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 3:03 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, October 5, 2022 2:57 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:56 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 28, 2022 9:42 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022**. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,
Justin

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Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Prosidyan®

(b)(4) BG Putty GPS

INSTRUCTIONS FOR USE

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

19. PERFORMANCE TESTING – ANIMAL

19.1 Performance Testing – Animal - EIT Cellular Titanium® Cages

Animal testing has not been performed to support the clearance of the EIT Cellular Titanium® Cages. This section is therefore not applicable.

19.2 Performance Testing – Animal - FIBERGRAFT® BG Putty

There have been no changes to the FIBERGRAFT® BG Putty since the prior submission (K170306). Because the subject device is identical to the previously cleared predicate, animal testing from the prior submission is adequate to support the current submission. No additional or new animal testing has been conducted.

It is important to note that clinical data is included in **Section 20** of this submission. The clinical data adequately supports the expanded indications proposed; therefore, no additional bench testing is needed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: http://secure-web.cisco.com/13xHjnhRldDjnGGnH7R5ZqNkixVsz99Ygt1mB1WfAdLpwdQ9Y9o5x7oL3bln5n_vH5FV2m5DFLnSJiJPKUyAc0jFxynkeZZjrPwRFPm78Aeozdv0OYgLGZ2mjjJD8K8g1283heGZTQdR_i2weLAFsGznqBi2tH_ahEZQjm5EoGjVJqVSOG_td7c7SDcfsvSk3/http%3A%2F%2Fwww.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: http://secure-web.cisco.com/13xHjnhRldDjnGGnH7R5ZqNkixVsz99Ygt1mB1WfAdLpwdQ9Y9o5x7oL3bln5n_vH5FV2m5DFLnSJiJPKUyAc0jFxynkeZZjrPwRFPm78Aeozdv0OYgLGZ2mjjJD8K8g1283heGZTQdR_i2weLAFsGznqBi2tH_ahEZQjm5EoGjVJqVSOG_td7c7SDcfsvSk3/http%3A%2F%2Fwww.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
Jennifer.houck@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: **https://secure-web.cisco.com/1AoYCJeHBvPUBot3aiufO1HxPC1DcEr44BgrvkctlOtGZxGwQAbFM79BIGMFJi_BCQjk63wiT2Fj6z1mT455FVNTHykTLwis0Ox8ABwMe_37kJboK38DvWgBWIL0QLvj48bhyquz2zFpx6fCJp3H6r4CLZklbGXJZP5qRFOjlls-psUXU1ucD6mj8ijP6yAC-5HvMTG5Tsj857f6VTnroEQ/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1831%26S%3DE**.*

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Jennifer,

I'll review when I'm back home in a few hours.

Thanks!

Justin

Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

202.552.5804

-------- Original message --------

From: "Houck, Jennifer" <Jennifer.Houck@fda.hhs.gov>

Date: 10/6/22 4:24 PM (GMT-05:00)

To: "Desjardins, Philip [JJCUS]" <pdesjard@ITS.JNJ.com>, Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>; Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

[cid:image003.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1BusqfVqlXsDhnFI61im95_DOSB7vfjZ2PpRr88TwSfigRmUVkiDAlM35gNJxCVBw2Bcv5wlgDdpgA1Z9FPodPGfrQYaIJl6CyLx2RYITfNiG0dltPxLlK4QGXiNHMIWQD2SJr6DSHUd_zMfFgsp0Cx875GtYF7QjkmkYwAqqDC4q6dDNl3kmxZGXxnoaZ0JG%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735467985%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iBcUzsBmz40pXLYQv%2FhyP2wbmLyrtwdjBg6ktOQDdiQ%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1LDBQLCEzZeH7HKRAilOC0w0YO70mJ5Cjzba1RXX8N7LTRijb2Wa_6JU2LGNR4Njc4qqjUolf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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bmLyrtwdjBg6ktOQDdiQ%3D&reserved=0>

[cid:image004.jpg@01D8D9A0.13200550]

If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP
here<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-
web.cisco.com%2F1NCywdwec0hmbg4QfZv592mOqJ850t6OGY4a9bhC4WnQ625tnb1NRDj8azRDIJHYDOW84Dq
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

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Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. (b)(4) (b)(4)

Thanks,

Justin

[cid:image007.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=j3aP%2FVmZPle9vXGu3dt%2BHFocTEi3Y4jrAMuL0l33F8E%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1LDBQLCEzZeH7HKRAilOC0w0YO70mJ5Cjzba1RXX8N7LTRijb2Wa_6JU2LGNR4Njc4qqjUolfPrv4fUw7i1P1P4-y5UfxoZFhtmkHSj6jhbe67maKo8TOxqhyn9aBSyfCmHaM6PGDNZVmbHf6b3rnTTMZdoeF7AtQzzaM2huiqNF9AxzK25f42H9HZ7i9OUATioNyxl7wrgGigA53brJRng/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=j3aP%2FVmZPle9vXGu3dt%2BHFocTEi3Y4jrAMuL0l33F8E%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,

Justin

[cid:image009.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gy%2FFVgIppuhmbYFMrwrOrWbOgHvwFHtgnaCFAgHX1ZI%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1LDBQLCEzZeH7HKRAilOC0w0YO70mJ5Cjzba1RXX8N7LTRijb2Wa_6JU2LGNR4Njc4qqjUolfPrv4fUw7i1P1P4-y5UfxoZFhtmkHSj6jhbe67maKo8TOxqhyn9aBSyfCmHaM6PGDNZVmbHf6b3rnTTMZdoeF7AtQzzaM2huiqNF9AxzK25f42H9HZ7i9OUATioNyxl7wrgGigA53brJRng/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gy%2FFVgIppuhmbYFMrwrOrWbOgHvwFHtgnaCFAgHX1ZI%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024
<pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image011.png@01D8D9A0.13471550]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=z5aDxlPQpsSqZ1pvDnTRzULS1GIhlX6ZY47RNKZcMzU%3D&reserved=0>

Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024
FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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%3D&reserved=0>.

Jennifer,

Email received. Working with DePuy to provide the answers/updated materials in a timely fashion.

Thanks!
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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Jennifer,

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Hi Justin,

Thanks for your response! (b)(4)

Hope to be in touch soon,
Jennifer

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
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Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

[cid:image001.png@01D8BC7F.0224BC20]<http://www.fda.gov/>

[cid:image002.jpg@01D8BC7F.0224BC20]<https://www.facebook.com/FDA>
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[cid:image006.jpg@01D8BC7F.0224BC20]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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7. CLASS III SUMMARY AND CERTIFICATION

The EIT Cellular Titanium® Cages and FIBERGRAFT® BG Putty are comprised of Class II devices per 21 CFR §888.3080; this section is therefore not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000030

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510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

B. Date Prepared

September 28, 2022

C. Device Name - CONDUIT™ Cages

Trade/Proprietary Name: CONDUIT™ Cages

Common/Usual Name: Intervertebral body fusion device

Regulatory Class: Class II per 21 CFR §888.3080

Review Panel: Orthopedic

Product Codes: ODP, MAX

D. Device Name - FIBERGRAFT™ BG Putty

Trade/Proprietary Name: FIBERGRAFT™ BG Putty

Common/Usual Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II per 21 CFR §888.3045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Review Panel: Orthopedic

Product Codes: MQV

E. Predicate Device Names

Primary Predicate: DePuy Synthes Spine, K201605, EIT Cellular Cervical Cage, EIT Cellular ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

Additional Predicate: Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Additional Predicate: Prosidyan Inc., K170306, FIBERGRAFT™ BG Putty Bone Graft Substitute

F. Device Description

The CONDUIT™ Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The CONDUIT™ Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous, or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed CONDUIT™ Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

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The purpose of this submission is to expand the indications for use of the CONDUIT™ Cages to include its use with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bonegraft.

G. Indications for Use

CONDUIT™ Cervical Cage

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

CONDUIT™ ALIF Cage

The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

CONDUIT™ TLIF Cage

The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and

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radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

CONDUIT™ LLIF Cage

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano- scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONDUIT™ T/PLIF Cage

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

FIBERGRAFT™ BG Putty

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty is not indicated for use in load-bearing applications; therefore, standard

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internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ BG Putty GPS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ GPS Cannula

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

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H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The purpose of this Traditional 510(k) is to expand the indications for use of the CONDUIT™ Cages to include its used with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The subject device is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. There are no differences in technological characteristics that will raise new concerns of safety or performance.

I. Materials

The CONDUIT™ Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001. The BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicate. The materials and manufacturing process for the CONDUIT™ subject devices are identical to that of the predicate device. Similarly, the materials and composition of the BG Putty device are identical to that of the predicate device and the manufacturing process remains substantially the same as that of the predicate. It is important to note that the manufacturing location of BG Putty was moved from Steris to Prosidyan (now DePuy Synthes), however the process has not changed.

J. Performance Data

The performance of the CONDUIT™ Cervical and Lumbar Cages and the FIBERGRAFT™ BG Putty have been assessed individually within their respective submissions (K201605, and K170306). Clinical data has been utilized to demonstrate the performance and safety of the expanded indications for use, which includes the use of the CONDUIT™ Cages with FIBERGRAFT™ BG Putty. The clinical data includes radiographic and clinical outcomes from a retrospective study and two investigator-initiated studies. The data provided includes 178 subjects and was collected from multiple sites across the United States (CA, TX, FL) to capture a variety of populations with diverse gender and racial/ethnic backgrounds that is representative of the intended users of the subject devices. The results of the data support the performance of the subject devices in intervertebral body fusion based on fusion and adverse event rates. Additional rationales were provided to justify the expanded indications based upon the clinical data results.

K. Conclusion

Based on the body of data presented throughout the submission, it has been determined that the subject devices are substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, and performance data.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

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(b)(4)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

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If interested in attending MCRA's NASS Cocktail Networking Reception on Thursday, Oct. 13th at 5:30pm at Celeste Rooftop Garden, please RSVP here<http://secure-
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af.com%2Fe%2FNASSnetworking>.

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

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Thank you for the update. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1A7DYRU7ic0ruA5sfeHNtr8tyYLObmmKfOfb8M1rEGhh7x-1FP_-G9Y7AJIyoZk3EtJGDZWcAEKiAkaYrhqOlTrNdfALc8FZSGCEbfuQe9PcNW0EPy1f-Y2AuzgxqMD32DFLS9jT8UnJ1cudakSvmHmRDDnnA9mciWumFwfpI8ZLVLD4Ve0hwqBkYq_GXfcXdw5gVn3f04JM58-cXf1094Q/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Cb165f1c405e64590950e08daa16a026a%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637999773981320347%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dMtpztD4aXZhAUtxppCDzG94ER1vwlRI1kw2hLVWsAY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Thanks for your patience as (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ed=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4) (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Justin

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Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thanks,

Justin

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>Justin Eggleton

Vice President, Spine Regulatory Affairs

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

	Type: Special Report	
Prosidyan®	Title: **Biocompatibility Impact Assessment- New Providence Manufacturing- FIBERGRAFT® BG Putty, FIBERGRAFT® BG Putty GPS, and GPS Cannula Products**	
	Document No: (b)(4)	Revision No: (b)(4)

Approvals	Date
(b)(4)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIC
WO66 RM4452
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3587

Premarket Notification 510(k) Review

Date: October 13, 2022

Reviewer: Jennifer Houck

510(k)# K222276 Subject: Traditional

Applicant: DePuy Spine	**Device Trade Name:** EIT Cellular Titanium Cages; FIBERGRAFT BG Putty
Contact Name: Justin Eggleton	**Contact Title:** Vice President, Spine Regulatory Affairs
Correspondent Firm: Mcra LLC	**Phone:** (202) 552-5800 **Email:** jeggleton@mcra.com
Received Date: July 29, 2022	**Due Date:** October 27, 2022
Pro Code(s): ODP **Class:** II **Reg #:** 888.3080	**Reg Name:** Intervertebral Body Fusion Device
Pro Code(s): MAX Class: II Reg #: 888.3080	Reg Name: Intervertebral body fusion device
Pro Code(s): MQV Class: II Reg #: 888.3045	Reg Name: Resorbable calcium salt bone void filler device

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K201605	MAX, ODP	EIT Cellular Titanium Cervical Cage, EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage	EIT Emerging Implant Technologies GmbH
K203714	MAX, PHM, OVD, MQV	NuVasive Thoracolumbar Interbody Systems: NuVasive CoRoent Thoracolumbar System, NuVasive CoRoent XL Interfixated System, Brigade System, Brigade Lateral System, BASE Interfixated Titanium System, Coalesce Thoracolumbar Interbody Fusion System, NuVasive Cohere Thoracolumbar Interbody System, NuVasive Modulus XLIF Interbody System, NuVasive Modulus TLIF Interbody System, NuVasive Modulus ALIF System, NuVasive Attrax Putty	NuVasive, Incorporated
K170306	MQV	FIBERGRAFT BG Putty Bone Graft Substitute	Prosidyan, Inc

Recommendation

I recommend that the EIT Cellular Titanium Cages; FIBERGRAFT BG Putty is/are Substantially Equivalent (SESE)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Digital Signature Concurrence Table (Doc ID: 04500.14.06)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Jennifer Houck -S Digitally signed by Jennifer Houck -S Date: 2022.10.13 10:01:50 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Hi Justin,

(b)(4)

(b)(4)

Hope to be in touch soon,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image002.png@01D8CDA1.B8051840]<http://secure-web.cisco.com/1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<http://secure-web.cisco.com/1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4c/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

[cid:image005.png@01D8CDA1.B8051840]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1KTE_bhxyaXCGk_clSeg_9TMQ1TslHRqADVR4tgIQdZqsv4wx3weGBD6QyQwnsS8cfV7AdiX__FOBbWHhf3KMQwk-8gJAFERY7IrV4Q39x69IpZTo9KxQLZ4Dqavggjd8IH_ANp4NQ5Z3d02W68CZOrqlFGHtW_PHYHQjNuDO0khaUGZHerkgawhaRLmNnmTqRo-MFK2D4VyNRGnKCSWA-g%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2qeqYogglz41xX1jxnCuCzoS%2F9gGl%2B1oNntE0Fh5tYc%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

The updated documents **(b)(4)**. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image006.png@01D8CDA1.B8051840]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=X4HLbo7W2axvB%2FzR90DPSYLcskTgkncqsITsf11G45Y%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

[cid:image006.png@01D8CDA1.B8051840]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=7Ye8vBjaYdk5NVTV%2BC517EJqpI94k2n6Evka7R8GhUY%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Web:
www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=7Ye8vBjaYdk5NVTV%2BC517EJqpI94k2n6Evka7R8GhUY%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2FUS_FDA&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377116244%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Ouff7rSoz%2BLwuheVWCiAV8nNKiawsx3cZVqfYYKO2wo%3D&reserved=0> [cid:image012.jpg@01D8CDA1.B7EF1F40]
<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.youtube.com%2Fuser%2FUSFoodandDrugAdmin&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377272468%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=vtbQbgIPhq9AT0g2UyHikLZZc24J4o%2B1LbLyMyl%2F4Qo%3D&reserved=0>
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[cid:image014.jpg@01D8CDA1.B7EF1F40]
<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFDA%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637987604377272468%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Eq%2FJrDjbD9WADgDWZMek61GxYMQrGBEk0hvpHqK1CaE%3D&reserved=0>

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7Ccc5f80044bb043e5cefb08da96588f0d%7C
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=HnMrDxnkTsKHYlmryhjabAs%2B4W2VECo8uV7aajY%2FZaw%3D&reserved=0>.

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U.S. FOOD & DRUG ADMINISTRATION

October 15, 2022

DePuy Spine
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
803 7th St NW
Washington, District of Columbia 20001

Re: K222276
Trade/Device Name: CONDUIT™ Cages and FIBERGRAFT™ BG Putty
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, MQV
Dated: July 29, 2022
Received: July 29, 2022

Dear Justin Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

K222276 – CONDUIT™ Cages and FIBERGRAFT™

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Jennifer,

Email received and we'll start working on this right away. I'll let you know if any follow-up questions.

Thanks,

Justin

[cid:image008.png@01D8A7FE.BDD58B10]<http://secure-web.cisco.com/1Ov_AFxpi88LUvkwQ71MDt9ki9i-eicNK237v_P7_3dZSCGqPCMFU-CQS3pXo0bGIVHV9cPLuAv8_fg2NU_cDrF8InAiG3PGXGdkEbzAZIIq4uVD_mix-RzoXvW8H_a9YbdOeq2cGz-vQrdozT8bxfhdJiDV45Syv5GH-TkHYXLpoIQ0Q-l9hVptK8PAreMZe/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1xo8sf2gKw2veZpMuncGc5-lxiENWq2XAME6HWQvoysMJKPiqYAU9LG_N0YsMRfW62Xy7tX3dzVbj7m-i1j3ts76jy6mbJHjdBoUndXLm2XmiAGZJxK3cBMMnofKGlJQwUcwjEntPPbX_KkVqF80Gk_1ZNBraBRFC2amDBm2H9ZeLhHEMCLL_psynrBtDqsam/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1Ov_AFxpi88LUvkwQ71MDt9ki9i-eicNK237v_P7_3dZSCGqPCMFU-CQS3pXo0bGIVHV9cPLuAv8_fg2NU_cDrF8InAiG3PGXGdkEbzAZIIq4uVD_mix-RzoXvW8H_a9YbdOeq2cGz-vQrdozT8bxfhdJiDV45Syv5GH-TkHYXLpoIQ0Q-l9hVptK8PAreMZe/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Thursday, August 04, 2022 12:06 PM

To: Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: K22276 - EIT Cellular Titanium Cages & FIBERGRAFT BG Putty - (b)(4) Interactive Request - Response due COB August 10, 2022

Good morning Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I'm requesting the above additional information by COB Wednesday August 10, 2022.

I'm available if there are questions regarding this request.

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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Jennifer,

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-Dt6fxhikXcfUkHZn6UASuge7mrqhPydugtNUHU1vH0ITZDg73hFxWgS9yFgSHn_xH2gKhqezkWfFg7B3DvR78MHqz9EpGpGEU6aOkw/http%3A%2F%2Fwww.mcra.com<http://secure-web.cisco.com/1ZqmLUtIx52WL9BsNspNEevnQPLhGqG5a07Ir3xHc5SdDiC1iVFdJXaMOsKPPVM-NLykpffrWkIb-N-nXBJ7gYN6fP2FKpomDn87jZil00-LDgzNqRsss7lnuY0faQR6L5Ur1Hm_7nRqKhCTP2gK9qIthnn54z6rpbC43-RSI1vDcIvhj1LpVWtJW5r8VI4Ttk04sucBOxvOc6VolahKTqg/http%3A%2F%2Fwww.mcra.com%2F>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Sent: Thursday, October 06, 2022 4:24 PM

To: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>; Justin Eggleton <jeggleton@mcra.com>

Cc: K222276@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Justin and Philip,

Apologies as I do have one more minor ask. (b)(4)

(b)(4)

Kind regards,

Jennifer

From: Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Sent: Wednesday, October 5, 2022 5:58 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>; Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

That is great to hear. If there are any additional requests or other news to share please include me on the email so that we can appropriately respond. Have a great day.

Phil

From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, October 5, 2022 3:03 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

I'm all good on my end and don't think I'll have any other requests for you. We hope to have a final recommendation out next week.

Thanks for checking in!

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, October 5, 2022 2:57 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Hope you're having a nice week! I'll be at a conference next week and not as diligent with emails, so want to check to see if there's anything I should request the team before I'm tied up.

Thanks,

Justin

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bmLyrtwdjBg6ktOQDdiQ%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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web.cisco.com%2F1NCywdwec0hmbg4QfZv592mOqJ850t6OGY4a9bhC4WnQ625tnb1NRDj8azRDIJHYDOW84Dq
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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 11:56 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Hi Justin,

Thank you! I'm crossing my fingers this was the last of our requests.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 28, 2022 9:42 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

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Jennifer,

Thank you for the update. **(b)(4)**

(b)(4)

Thanks,

Justin

[cid:image006.png@01D8D9B6.895E17F0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=j3aP%2FVmZPle9vXGu3dt%2BHFocTEi3Y4jrAMuL0l33F8E%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-Dt6fxhikXcfUkHZn6UASuge7mrqhPydugtNUHU1vH0ITZDg73hFxWgS9yFgSHn_xH2gKhqezkWfFg7B3DvR78MHqz9EpGpGEU6aOkw/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F17VerSJJKKQ1IAOhbN0k8IO7J-GOkYkAAKWEKYo5dq2G8aRBclPYSx-qyEqPZo3S2fOaANq-QYn9IyO1AJFRoa97Q63mroizvQhX0sijOR9oQQaKQsptHOADH2JNUk-rsY2Ap1dqGpDaA6WDMl93ahDZul5079ePXt5SqNHZVcBFpvsxsyIoCwADRgzEL12aSKyGPIPVPghWs0mli82VdPQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=j3aP%2FVmZPle9vXGu3dt%2BHFocTEi3Y4jrAMuL0l33F8E%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 28, 2022 8:51 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4831; Released by CDRH on 10-15-2024

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Wednesday, September 21, 2022 9:23 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-Dt6fxhikXcfUkHZn6UASuge7mrqhPydugtNUHU1vH0ITZDg73hFxWgS9yFgSHn_xH2gKhqezkWfFg7B3DvR78MHqz9EpGpGEU6aOkw/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1XEpaBWBh2I54Mzh3Kx8O86bH4NRuoO3LU_nYkj6Wuys3LG7h_si_aewy-2hlkLjJcqwY29Fa9PvHvO2E7aOAJ2PffuJbHrzPzZlB7Mnq3_o5QY9zYHhAZ-UY7v6dINLPrzoRYXVRBtppRIrh7_-dnGTUk4SL7dhOhLG20zahKydlMs_Emei2Mmyi5rdhxJvJR9_EELe2CGR5xN1dWYm0wT3d7nVbJdMGxHBqMPMBf4

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Wednesday, September 14, 2022 9:54 AM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

Please address the above items by 5 PM EST September 21, 2022. Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Sunday, September 11, 2022 7:33 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4)

(b)(4)

Thanks,

Justin

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Vice President, Spine Regulatory Affairs

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803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, September 06, 2022 1:09 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

(b)(4)

I'm also available for any questions related to this request.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com<mailto:pdesjard@ITS.JNJ.com>>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

The updated documents to align the indications are attached for your review. Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image013.png@01D8D9B6.895E17F0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735624172%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=z5aDxlPQpsSqZ1pvDnTRzULS1GIhlX6ZY47RNKZcMzU%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:53 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,

Justin

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[cid:image014.png@01D8D9B6.895E17F0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A7UShKuxvZewhRVc6qsSFM%2FjQfNih3p1kag84%2F4VgeM%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

MCRA, LLC

803 7th Street NW

Washington, DC 20001

Office: 202.552.5804 | Fax: 202.552.5798

Web: http://secure-web.cisco.com/1-A0nuI6MCxOSb7Ef7oI8TzOxDz5dX-mdKFM6q3wRcRDXOUJ7UEbOlgkA_yV-jXxM33QzXa5kqVgPVVRivjDe_x_V7nDJ2QGpa0VUGRAkP5Sw_o_-Dt6fxhikXcfUkHZn6UASuge7mrqhPydugtNUHU1vH0ITZDg73hFxWgS9yFgSHn_xH2gKhqezkWfFg7B3DvR78MHqz9EpGpGEU6aOkw/http%3A%2F%2Fwww.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A7UShKuxvZewhRVc6qsSFM%2FjQfNih3p1kag84%2F4VgeM%3D&reserved=0>

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov<mailto:Jennifer.Houck@fda.hhs.gov>>

Sent: Tuesday, August 30, 2022 2:45 PM

To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Kind regards,

Jennifer

Jennifer Houck, M.S. (she/her)

Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team

DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4452 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-3587

Jennifer.houck@fda.hhs.gov<mailto:Jennifer.houck@fda.hhs.gov>

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[cid:image016.jpg@01D8D9B6.895E17F0]<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.facebook.com%2FFDA&data=05%7C01%7Cjeggleton%40mcra.com%7C70a417a48f83439bd2ab08daa7d8c3e0%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C638006846735780827%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=C9K%2FfaGWQsejC1B%2BR4NfAockC5kNgxMjWeKEzsvfUzQ%3D&reserved=0> [cid:image017.jpg@01D8D9B6.895E17F0]
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

15. BIOCOMPATIBILITY

15.1 Biocompatibility - EIT Cellular Titanium® Cages

The biocompatibility of the EIT Cellular Titanium® Cages is identical to the predicate devices (K201605).

There have been no changes to the EIT Cellular Titanium® Cages from the prior submission (K201605) that impacts the biocompatibility of the subject device. The prior submission, K201605, utilized the information from K172888 to establish biocompatibility of the subject device. Therefore, the biocompatibility of the EIT Cellular Titanium® Cages has been evaluated via a risk analysis process as outlined by FDA in Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff issued on September 4, 2020.

The EIT Cellular Titanium® Cages and instruments are identical to the EIT Cellular Titanium® Cages and instruments (K201605, and K172888) medical devices in its final finished form in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

The table below provides an overview of the EIT Cellular Titanium® Cages and instruments nature of body contact and materials.

Table 1: Overview of Nature of Body Contact and Materials

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15.2 Biocompatibility - FIBERGRAFT® BG Putty

The biocompatibility of the FIBERGRAFT® BG Putty is identical to the predicate devices (K170306).

(b)(4)

As detailed below, the biocompatibility of FIBERGRAFT® BG Putty product was previously established through ISO 10993 testing of the finished putty product, which remains the same as previously cleared. As submitted to FDA in K170306 and summarized below in **Table 2**, all biocompatibility testing showed acceptable results in relation to established criteria with no adverse biological reactions.

Table 2: Biocompatibility Testing of FIBERGRAFT® BG Putty

	Intracutaneous Irritation	Acute Systemic Toxicity	Sensitization	Genotoxicity (Bacterial Reverse Mutation)	Genotoxicity (Mouse Lymphoma Assay)
(b)(4)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 000111

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	Intracutaneous Irritation	Acute Systemic Toxicity	Sensitization	Genotoxicity (Bacterial Reverse Mutation)	Genotoxicity (Mouse Lymphoma Assay)
(b)(4)					

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer,

Thank you for the update (b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:51 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM October 3, 2022

Good morning Justin,

Thanks for your patience as (b)(4)

(b)(4)

We are asking that you provide your response to the above requests by 8 AM Monday October 3, 2022.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Wednesday, September 21, 2022 9:23 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

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Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001

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Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022.** Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4) (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, August 30, 2022 2:45 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Good afternoon Justin,

We are currently in the middle of our review for K222276 and have one item we'd like to address interactively. Please see the following:

(b)(4)

Kind regards,
Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

Restorative, Repair, Trauma and Fracture Fixation Devices Team
DHT6C: Division of Restorative, Repair, and Trauma Devices | OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4452 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-3587
jennifer.houck@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: ***https://www.research.net/s/cdrhcustomerservice?ID=1831&S=E***.

Jennifer,

Thanks again for the ability to interact with you and the team on this. (b)(4)

(b)(4)

Thanks,
Justin

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
Web: www.mcra.com

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From: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:54 AM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 5 PM September 21, 2022

Hi Justin,

Thanks for your response and I appreciate your assistance on these asks!

(b)(4)

Please address the above items by **5 PM EST September 21, 2022.** Also note, currently, these are the last of our requests. If the review team identifies other items for you to address interactively, they will likely be minor.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Sunday, September 11, 2022 7:33 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

I hope you had a nice weekend. (b)(4) We appreciate the continued interaction and will remain on standby for questions as they arise.

Thanks,
Justin

Records processed under FOIA Request 2023-4331; Released by CDRH on 10-15-2024

Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5804 | Fax: 202.552.5798
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From: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Sent: Tuesday, September 06, 2022 1:09 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hello Justin,

(b)(4)

I'm also available for any questions related to this request.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Friday, September 2, 2022 10:35 AM
To: Houck, Jennifer <jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,
Justin

Justin Eggleton
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Sent: Tuesday, August 30, 2022 2:53 PM
To: Justin Eggleton <jeggleton@mcra.com>
Cc: K222276@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

Hi Justin,

Much appreciated! Look forward to hearing back.

Kind regards,
Jennifer

From: Justin Eggleton <jeggleton@mcra.com>
Sent: Tuesday, August 30, 2022 2:50 PM
To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>
Cc: K222276@docs.fda.gov
Subject: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

Email received, thank you. I just passed the questions on to DePuy and we will be back with the corrected documents shortly.

Thanks,
Justin

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Subject: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer

Jennifer Houck, M.S. (she/her)
Biomedical Engineer

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Hi Justin,

Thanks for the modified documents. I'll take a look and follow-up with you if we need anything else.

Thank you again and hope you have a wonderful long weekend,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com>

Sent: Friday, September 2, 2022 10:35 AM

To: Houck, Jennifer <Jennifer.Houck@fda.hhs.gov>

Cc: K222276@docs.fda.gov; Desjardins, Philip [JJCUS] <pdesjard@ITS.JNJ.com>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Jennifer,

(b)(4) Let me know if any questions. Hope you get to enjoy Labor Day weekend!

Thanks,

Justin

[cid:image002.png@01D8BED7.084E39A0]<http://secure-web.cisco.com/1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G/http%3A%2F%2Fwww.mcra.com%2F>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Washington, DC 20001

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Web: www.mcra.com<http://secure-web.cisco.com/1y9udK829rh08FDO0-Qx2TXxxjOZWJWKB3VFs9lSOymrYTYrMmxddc45gDwWZEV0DtK9FnbInTL4SqID11-xd0XfsZOglWsHgRM1H4hKlaMjLIdIw1VQZk8prqd9prVfmHNQt5g2U-VGWF3QaB5ak8gq-KWEXCBKrcrhcVzqvxPVUnGN0S1ddPrYZbGfqGB-G/http%3A%2F%2Fwww.mcra.com%2F>

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Sent: Tuesday, August 30, 2022 2:53 PM

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To: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222276 - DePuy Spine - EIT Cellular Titanium Cages and FIBERGRAFT BG Putty - Interactive Request - Response due 8 AM September 6, 2022

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Kind regards,

Jennifer

From: Justin Eggleton <jeggleton@mcra.com<mailto:jeggleton@mcra.com>>

Sent: Tuesday, August 30, 2022 2:50 PM

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Cc: K222276@docs.fda.gov<mailto:K222276@docs.fda.gov>

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Jennifer,

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Thanks,

Justin

[cid:image010.png@01D8BED7.084E39A0]<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=aVS4ag2WlCnvmLd9enMuIzb3QZYVeEr1qJesctXjmvE%3D&reserved=0>Justin Eggleton

Vice President, Spine Regulatory Affairs

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Office: 202.552.5804 | Fax: 202.552.5798

Web: www.mcra.com<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsecure-web.cisco.com%2F15PVEyASkKWL1nsdjx6Bc8nQ6z-herb6BHI-M3QeEWXenHvpbcfjik-dQP4uHtgdi9LEia0a66F6hWLAOOK8dxgHx3-IgOo7mGS3mq7TtTCyGIpfxFCqZOovwPM497f3hzgVJzDM67E-dFmF23ejl8Xs0unY3UkReFiUlQJR0lw3wDf1d56_eB2RqDjCNA5oPs7VsoOk2PAyUeOCcurTeCQ%2Fhttp%253A%252F%252Fwww.mcra.com%252F&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637974823712987103%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%

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Jennifer Houck, M.S. (she/her)

Biomedical Engineer

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Ph: (301) 796-3587

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<https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FAboutFD
A%2FContactFDA%2FStayInformed%2FRSSFeeds%2Fdefault.htm&data=05%7C01%7Cjeggleton%40mcra.
com%7C2c87872056c841a90ed208da8ab8d4af%7C187c2674238d47e68b44e81c783bc9a4%7C0%7C0%7C637
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D&reserved=0>

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ection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3
D1831%26S%3DE&data=05%7C01%7Cjeggleton%40mcra.com%7C2c87872056c841a90ed208da8ab8d4af%7C
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