

March 14, 2024</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Michael Molyneaux-Francis.</p>

<p>*** This is a system-generated email notification ***</p>



Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: August 21, 2023

Reviewer: Michael Molyneaux-Francis

510(k)# K231850 **Subject:** Traditional

Applicant: Globus Medical Inc

Contact Name: Jennifer Antonacci

Correspondent Firm: Globus Medical Inc

Received Date: June 23, 2023

Pro Code(s): NKG **Class:** II **Reg #:** 888.3075

Pro Code(s): KWP **Class:** II **Reg #:** 888.3050

Pro Code(s): OLO **Class:** II **Reg #:** 882.4560

Device Trade Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Title: Group Manager, Regulatory Affairs

Phone: (610) 930-1800 **(b)(6)** **Email:** **(b)(6)**

Due Date: September 21, 2023

Reg Name: Posterior Cervical Screw System

Reg Name: Spinal Interlaminar Fixation Orthosis

Reg Name: Stereotaxic Instrument

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161591	NKG, KWP, OLO	QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K211957	NKG, KWP, OLO	QUARTEX Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K200047	OLO, HAW	ExcelsiusGPS Cranial 1.0 Module	Globus Medical Inc.
K211616	OLO	ExcelsiusHub	Globus Medical Inc.

Recommendation

(b)(5)

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Digital Signature Concurrence Table (Doc ID: 04500.16.00)

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.

For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: Major Deficiencies (#8, #9) and Minor Deficiencies (#2, #3, and #4) that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).

I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.

Reviewer Sign-Off

Michael S.
Molyneaux-francis -S
Digitally signed by Michael S.
Molyneaux-francis -S
Date: 2023.08.21 08:03:26 -04'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K231850

Device Name

QUARTEX® Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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.**

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

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.**Indications for Use**510(k) Number (if known)
K231850Device Name
ExcelsiusGPS®

Indications for Use (Describe)

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

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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Food and Drug Administration

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Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K231850

Device Name

ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Type of Use (Select one or both, as applicable)

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(b)(4)



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

Convert to PDF

Globus Medical Inc
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K231850

Trade/Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS®
Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, KWP, OLO

Dated: February 9, 2024

Received: February 12, 2024

Dear Jennifer Antonacci:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

K231850 - Jennifer Antonacci

Page 3

Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

QUARTEX® Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Type of Use (Select one or both, as applicable)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 07/31/2026

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K231850

Device Name

ExcelsiusGPS®

Indications for Use (Describe)

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

Type of Use (Select one or both, as applicable)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name
ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Type of Use (Select one or both, as applicable)

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Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: March 11, 2024

Reviewer: Michael Molyneaux-Francis

510(k)# K231850/S001 **Subject:** Traditional

Applicant: Globus Medical Inc

Contact Name: Jennifer Antonacci

Correspondent Firm: Globus Medical Inc

Received Date: February 12, 2024

Pro Code(s): NKG **Class:** II **Reg #:** 888.3075

Pro Code(s): KWP **Class:** II **Reg #:** 888.3050

Pro Code(s): OLO **Class:** II **Reg #:** 882.4560

Device Trade Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Title: Group Manager, Regulatory Affairs

Phone: (610) 930-1800; **Email:** (b)(6)

Due Date: March 14, 2024

Reg Name: Posterior Cervical Screw System

Reg Name: Spinal Interlaminar Fixation Orthosis

Reg Name: Stereotaxic Instrument

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161591	NKG, KWP, OLO	QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K211957	NKG, KWP, OLO	QUARTEX Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K200047	OLO, HAW	ExcelsiusGPS Cranial 1.0 Module	Globus Medical Inc.
K211616	OLO	ExcelsiusHub	Globus Medical Inc.

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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) GLOBUS MEDICAL INC Globus Medical Inc. Valley Forge Business Center 2560 General Armistead Ave. Audubon PA 19403 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4954	2. CONTACT NAME Kelly Baker 2.1 E-MAIL ADDRESS (b)(6) 2.2 TELEPHONE NUMBER (include Area code) 610-930-1800 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 610-415-5322
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) <u>Select an application type:</u>	
☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request	3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 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 ☒ 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? ☒ 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 ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ 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 ☒ NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Paperwork Reduction Act (PRA) Staff
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[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)

25-Apr-2023

Form FDA 3601 (07/22)

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Valley Forge Business Center
2560 General Armistead Avenue Audubon, PA 19403
Phone: 610.930.1800 Fax: 610.930.2042
Order Fax: 610.930.2041
www.globusmedical.com

June 22, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: QUARTEX Additional Implants Premarket Notification

Dear Sir/Madam,

Globus Medical Inc. hereby submits this **Traditional 510(k)** to request clearance for **QUARTEX Additional Implants**, which are line extensions to the previously cleared QUARTEX Occipito-Cervico-Thoracic Spinal System, as well as additional instruments for use with ExcelsiusGPS or ExcelsiusHub. These devices are considered Class II under panel code 87 which is with the same classification regulation as the predicate devices. In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, this submission constitutes a Premarket Notification for QUARTEX Additional Implants. There have been no prior submissions for this device. An eCopy is enclosed. A draft Refuse to Accept checklist is included for convenience.

Documentation is provided to support a claim of substantial equivalence to commercially available predicate devices, including the QUARTEX system. The intent to market this device and the information contained in this submission are considered proprietary, confidential, and protected from public disclosure in accordance with the provisions for confidentiality under 21 CFR §807.95 and other applicable provisions of the law.

Globus believes that the information contained in this submission is sufficient for the agency to find that the subject implants are substantially equivalent to the predicate devices. If additional information is required, please contact me at (610) 930-1800 (b)(6) or by email at (b)(6). An alternate contact, Kelly Baker, PhD, Senior Vice President of Regulatory and Clinical Affairs, may be reached at (610) 930-1800 (b)(6) or by email at (b)(6).

Sincerely,

(b)(6)

Jennifer Antonacci, PhD
Group Manager, Regulatory Affairs
Globus Medical, Inc.

*Contains Nonbinding Recommendations***Appendix A. Acceptance Checklist for Traditional 510(k)s****(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 application.

510(k)#:**Date Received by DCC:****510(k) Lead Reviewer:****Center:****Office:****Division:****Decision:** Accept _____ Refuse to Accept _____**If Accept, notify the submitter.****If Refuse to Accept, notify submitter electronically and include a copy of this checklist.****Is an Addendum attached?:** Yes No

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.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified 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. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☒	☐	

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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 the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			
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. <i>Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> 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. <i>Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☐	☐	☒
Comments:			

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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 division 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

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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 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.

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.	☒	☐	1
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. <i>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...).</i>	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	
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.

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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.		Yes	No	N/A	*Page #
*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.					
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐		
	Comments:				
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	☒	☐		6
b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐		6, 9
	Comments: <i>see cover letter, 510(k) summary, section VI</i>				
3.	Submission contains an Indications 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). <i>See recommended format</i> (https://www.fda.gov/media/86323/download).	☒	☐		2-5
	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.	☒	☐		
	Comments: <i>see section III</i>				

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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.		Yes	No	N/A	*Page #
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l). <i>See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).</i>	☒	☐		1
Comments:					
6.	Submission is a class III 510(k) Device. <i>Select "N/A" only if submission is not a class III 510(k).</i>	☐		☒	
a.	Contains class III Summary and Certification per 21 CFR 807.87(k). <i>See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).</i>	☐	☐	☒	
Comments:					
7.	Submission contains clinical data. <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.</i>	☐		☒	
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. <i>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.</i>	☐	☐	☒	

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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	*Page #
	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 <i>Title VIII of FDAAA, Sec. 801(j)</i>.	☐	☐	☒	
	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. <i>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.</i> <i>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>	☐		☒	

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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	*Page #
		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 it was not subject to the regulations under 21 CFR 56.104 or 56.105). <u>OR</u> The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. <i>Select "N/A" if the clinical investigations were conducted solely OUS.</i>	☐	☐	☒	
		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). <u>OR</u> The submission includes a waiver request in accordance with 21 CFR 812.28(c). <u>OR</u> 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. <i>Select "N/A" if the clinical investigations were conducted solely inside the US.</i>	☐	☐	☒	
Comments:							

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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	*Page #
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. <i>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, available at https://www.fda.gov/media/72421/download). 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).</i>	☒	☐		
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. <i>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.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	☒	
Comments: <i>See Cover Letter</i>					
9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). <i>This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.</i>	☒		☐	
a.	The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐	<i>Att. D</i>

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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	*Page #
		i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," 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 "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," 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).	☐		☒	
		i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
Comments:							
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.						☒	
	10.	Submission identifies the product as a combination product.		☐	☐		
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.		☐		☐	

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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	*Page #
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐		
			Comments:				
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. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☒		☐	
		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. <i>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.</i>	☒	☐	☐	11-27

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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.		Yes	No	N/A	*Page #
*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.					
	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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	11-27
	Comments: <i>See Section X</i>				
	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).	☒	☐		11-27
	Comments:				
	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.	☒	☐		11-27
	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.	☒	☐		11-27
	c. A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>	☒	☐	☐	11-27

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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	*Page #
	d. Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. <u>OR</u> 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). <i>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.</i>	☒	☐		11-27
	Comments: See Section X, Att. H				
15.	Device is intended to be marketed with accessories and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>	☒		☐	Att. H
	a. Submission includes a list of all accessories to be marketed with the subject device.	☒	☐		Att. H
	b. Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. <i>Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	☒	☐	☐	Att. H
	c. A 510(k) number is provided for each accessory that received a prior 510(k) clearance. <u>AND</u> A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐		Att. H
	Comments: See Att. H				

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*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.					
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. <i>Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i>	☒	☐		6
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.	☒	☐		
	Comments: <i>See 510(k) Summary d Section x</i>				
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)]. <i>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.</i>				

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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	*Page #
	a.	Indications for use <i>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.</i>	☒	☐		11
	b.	Technology, including technical specifications, features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the 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.</i>	☒	☐		16, 26
		Comments:				
D.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)					
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		Att. B
	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).	☒	☐		Att. B
	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. B

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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	*Page #
	Comments:				
19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		Att. B.
	Comments: <i>See Attachment B</i>				
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, " <u>Use of Symbols in Labeling</u> " (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). <i>Select "N/A" if not indicated for prescription use.</i>	☒	☐	☐	Att. B
	Comments: <i>See Attachment B</i>				
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. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☒		☐	Att. B
	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. <i>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.</i>	☒	☐	☐	Att. B

Contains Nonbinding Recommendations

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 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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	
	Comments:				
	22. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>	☐	☐	☒	
	Comment:				
E.	Sterilization <i>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.</i>			☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*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. Submission states that the device and/or accessories, if applicable, are: (<i>one of the below must be checked</i>) ☒ 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. <i>If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."</i> <i>The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:</i> <i>Supplied sterile and requires reprocessing prior to subsequent patient use</i> <i>Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use</i> <i>Reusable medical device (single-user) reprocessed between each use</i> <i>Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use</i> <i>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.</i>		☐			Att-A
Comments: <i>See Attachment A</i>					
23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

Contains Nonbinding Recommendations

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. Identification of device and/or accessories, if applicable, that are provided sterile. <i>Select "N/A" if no part of the device or accessories are provided sterile.</i>	☒	☐	☐	Att. A + Att. H
	b. Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. <i>Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.</i>	☒	☐	☐	Att. A + Att. H
	c. Identification of device and/or accessories, if applicable, that are reusable. <i>Select "N/A" if no part of the device or accessories, are reusable.</i>	☐	☐	☐	
	Comments: <i>See Attachment A & Attachment H</i>				
24.	If the device and/or accessories, if applicable, are provided sterile: <i>Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.</i>			☐	
	a. Sterilization method is stated for each device (including dose for radiation sterilization)	☒	☐		Att. A
	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). <i>Note: the sterilization validation report is not required.</i>	☒	☐		Att. A
	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. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	☐	☐	☒	
	d. Sterility Assurance Level (SAL) stated	☒	☐		Att. A
	e. Submission includes description of packaging	☒	☐		Att. A

Contains Nonbinding Recommendations

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 #
	f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amoebocyte lysate [LAL]). <i>Select "N/A" if not labeled "non-pyrogenic."</i>	☐	☐	☒	
		Comments:				
25.		If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: <i>Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.</i>			☐	
	a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.</i>	☒	☐	☐	Att. A + Att. B
	b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.</i>	☒	☐	☐	Att. A + Att. B
	c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.</i>	☒	☐	☐	Att. A + Att. B

Contains Nonbinding Recommendations

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 #
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "<u>Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications</u>" (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). <i>Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐		☒	
		i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. <i>Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐	☐	☐	
		Comments: <i>See Attachment A & Attachment B</i>					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☒		☐	

Contains Nonbinding Recommendations

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.	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. <i>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.</i>	☒	☐	☐	Att. A + Att. B
	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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	Att. A + Att. B
		Comments: See Attachment A + Attachment B				
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.	☒	☐		Att. A

Contains Nonbinding Recommendations

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 #
	Comments: <i>see Attachment A</i>				
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. <i>Select "N/A" if the device is not provided sterile.</i>	☐	☒	☐	<i>Att. A</i>
	Comments: <i>see Attachment A</i>				
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.). <u>OR</u> Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐	☐	<i>Att. A</i>
	Comments: <i>see Attachment A.</i>				
G.	Biocompatibility <i>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.</i>			☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*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. Submission states that there: <i>(one of the below must be checked)</i> ☒ 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 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>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 tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."</i> <i>An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.</i>			☐		28-33
Comments: <i>See Section X</i>					
30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		28-33
Comments: <i>See Section X</i>					
31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☒	☐		28-33
Comments: <i>See Section X</i>					

Contains Nonbinding Recommendations

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 #
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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" 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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" 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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" provided for each completed test. <u>OR</u> 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).	☒	☐		28-33
	Comments:				
H.	Software				

Contains Nonbinding Recommendations

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 states that the device: <i>(one of the below must be checked)</i> ☐ Does contain software/firmware ☒ 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. <i>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."</i>			☐		9
Comments:					
33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
Comments:					
34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "<u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u>," available at <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices</u>, 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). <i>Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.</i>	☐	☐		

Contains Nonbinding Recommendations

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 #
Comments:					
I.	Cybersecurity				
	Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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. <i>If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."</i>	☐		9	
	35. All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. OR 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).	☐	☐		
Comments:					
J.	Electrical Safety and EMC				

Contains Nonbinding Recommendations

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 #
	Electrical Safety: Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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 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. <i>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."</i>		☐		9
36.	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:				

Contains Nonbinding Recommendations

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 #
EMC: Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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 This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>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."</i>			☐		9
Comments:					
37.	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:					

Contains Nonbinding Recommendations

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 #
K.	Performance Data General <i>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 L.</i>			☐	
Comments:					
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. Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.	☒	☐	☐	Att E + 34-36
a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). Select "N/A" if the submission does not include performance data.	☒	☐	☐	Att E 34-36
Comments: See section X and Attachment E					

Contains Nonbinding Recommendations

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 #
39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☒		☐	
a.	The submission addresses performance data 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. <i>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.</i>	☒	☐	☐	Att-E
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. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls 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.</i>	☒	☐	☐	Att-E
Comments:					

Contains Nonbinding Recommendations

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 #
40.	If literature is referenced in the submission, submission includes: <i>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.</i> <i>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.</i>				☒	
	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:					
41.	For each completed animal study, the submission provides the following: <i>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.</i>				☒	
	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:					

Contains Nonbinding Recommendations

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 #
L.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))				
	Submission indicates that device: <i>(one of the below must be checked)</i> ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>				9
42.	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:				
43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐	☐	☐	

Contains Nonbinding Recommendations

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.	The submission addresses performance data 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. <i>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.</i>	☐	☐	☐	
		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. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☐	☐	☐	
		Comments:					

Contains Nonbinding Recommendations

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

Globus Medical 510(k) Premarket Notification

QUARTEX Additional Implants

TRADITIONAL 510(k)

Submitted to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted by:

Globus Medical, Inc.
Valley Forge Business Center
2560 General Armistead Ave.
Audubon, PA 19403
(610) 930-1800

Contact Name:

Jennifer Antonacci, Ph.D.

(b)(6)

Secondary Contact Name:

Kelly J. Baker, Ph.D.

(b)(6)

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I. Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required By 21 CFR §807.87(k)]

I, Jennifer Antonacci, Ph.D., certify that, in my capacity as Group Manager, Regulatory Affairs, of Globus Medical, Inc., 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)

Premarket Notification [510(k)] Number

Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

II. Indications for Use

The Indications for Use Statements (Form 3881) are provided on the following pages and are suitable for publication on the FDA website.

III. 510(k) Summary

The 510(k) Summary is provided on page 6 and is suitable for publication on the FDA website.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

QUARTEX® Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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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Food and Drug Administration

Indications for Use

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See PRA Statement below.

(b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name
ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion 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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510(k) Summary: QUARTEX® Additional Implants

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(b)(4)

(b)(4)

IV. Device Name

QUARTEX Occipito-Cervico-Thoracic (OCT) Spinal System

V. Registration Number

Globus Medical's FDA registration number is 3004142400.

VI. Classification Information

Per the Code of Federal Regulations, Title 21, the classification of the subject and predicate QUARTEX OCT Spinal System is as follows:

§888.3075 Posterior Cervical Screw System

Product Code: NKG; Regulatory Class: II; Panel Code: 87

§888.3050 Spinal Interlaminar Fixation Orthosis

Product Code: KWP; Regulatory Class: II; Panel Code: 87

Per the Code of Federal Regulations, Title 21, the classification of the subject and predicate ExcelsiusGPS Instruments is as follows:

§882.4560 Stereotaxic instrument

Product Code: OLO; Regulatory Class II; Panel Code 87

Subject QUARTEX implants are not *in vitro* diagnostic devices, do not include software, and do not require EMC and electrical safety evaluation.

VII. Performance Standards

Performance of subject QUARTEX implants was evaluated in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004, and ASTM F1717 (Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model).

Subject QUARTEX implants are manufactured from titanium alloy per (b)(4), or (b)(4) stainless steel per (b)(4) (rods only); or cobalt chromium molybdenum alloy per (b)(4).

A list of recognized consensus standards is provided in **Attachment D** for standards referenced throughout this submission.

VIII. Proposed Labels / Labeling

See **Attachment B** for copies of the proposed package label, device specific insert, and surgical technique manual. Indications for the subject devices are similar to those of the predicate devices. The subject devices qualify for exemption from including directions for a layperson per 21 CFR 801 Subpart D.

(b)(4)

X. Description of the Device

Overview

The **predicate QUARTEX Occipito-Cervico-Thoracic (OCT) System** (K161591, K211957) is a posterior cervical stabilization system for use in the OCT spine (occiput-T3). Implants include polyaxial screws, polyaxial shoulder screws, hooks, locking caps, (b)(4), and various specialized connectors (**Figure 1**). QUARTEX screws are cleared for use with ExcelsiusGPS using navigated instruments. The implants may be connected to larger diameter rods using connectors. QUARTEX implants are manufactured from titanium (Ti) alloy, stainless steel, or cobalt chromium molybdenum (CoCr) alloy.

(b)(4)

Figure 1. Predicate QUARTEX implants and full construct.

The **reference CREO Stabilization System**, including CREO 4.75, MIS, Threaded and AMP (K143633, K124058) is a modular thoracolumbar stabilization system that includes (b)(4), a variety of polyaxial and monoaxial screws (**Figure 2**), and connectors that secure two rods or extend a rod. Rods are available in titanium alloy, stainless steel, or CoCr alloy. CREO screws are cleared for use with ExcelsiusGPS using navigated instruments.

(b)(4)

Figure 2. Reference CREO screws and rods (examples).

The **subject QUARTEX implants** are additional screws and rods that may be used with previously cleared QUARTEX implants, and include (b)(4) smaller diameter (b)(4) polyaxial screws and (b)(4) (b)(4) and MIS rods (**Figure 3**). Implants may be connected to larger diameter rods using cleared connectors. Instruments for placing and reducing new MIS rods and for navigating implants with ExcelsiusGPS are included. Subject screws are manufactured from Ti alloy, and the MIS rods are manufactured from Ti alloy, stainless steel, or CoCr alloy. Subject QUARTEX implants have the same indications for use as the predicate QUARTEX system.

(b)(4)

Figure 3. Subject QUARTEX screws and rods.

A complete list of components and confidential engineering drawings of the subject devices are provided in **Attachment H**. The draft QUARTEX surgical technique manual and draft ExcelsiusGPS User Manual Supplement are provided in **Attachment B**.

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Attachment C: Commercially Available Device Information

The SE Letters and 510(k) Summaries for the following commercially available devices are included in this attachment:

Primary Predicate

- QUARTEX Occipito-Cervico-Thoracic (OCT) System (K161591)

Additional Predicates

- QUARTEX OCT System (K211957)
- ExcelsiusGPS (K171651, K200047)
- ExcelsiusHub (K210606)

Reference Device

- CREO Stabilization System (K143633, K124058)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

September 21, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K161591

Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Regulatory Class: Unclassified

Product Code: NKG, KWP, OLO

Dated: September 7, 2016

Received: September 8, 2016

Dear Dr. Baker:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Kelly J. Baker, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K161591

Device Name

QUARTEX™ Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K161591

Device Name
Globus Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX, CREO, REVERE, REVOLVE, ELLIPSE, and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary: QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus Navigation Instruments

Company: Globus Medical, Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: September 15, 2016

Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Pre-Amendment Device
Cervical Pedicle Screw Spinal Fixation Orthosis
Product Code: NKG
Regulatory Class: Unclassified

Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
Product Code: KWP
Regulatory Class: II, Panel Code: 87

Globus Navigation Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II; Panel Code: 87

Predicates: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Primary predicate: ELLIPSE® OCT Spinal System (K150552)
Additional predicates: Synapse OCT System (K142838)
Reference: H-LINK™ Integrated Rod (K073517)
PROTEX CT® (K050391)

Globus Navigation Instruments
Additional predicate: Globus Navigation Instruments (K153203)

Purpose:

The purpose of this submission is to request clearance for QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants and instruments, and Globus Navigation instruments for use with the Medtronic StealthStation® System.

Device Description:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System consists of 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps, QUARTEX™ H-LINK™ Integrated Rod and occipital plates. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537).

QUARTEX™ constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX®, CREO®, REVERE®, or BEACON® Systems using corresponding connectors.

The QUARTEX™ System include manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Globus Navigation Instruments are nonsterile, reusable instruments that can be operated manually and are intended to be used with the Medtronic StealthStation® System.

Indications for Use:**QUARTEX™ Occipito-Cervico-Thoracic Spinal System**

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX, CREO, REVERE, REVOLVE, ELLIPSE, and PROTEX CT Stabilization Systems) during spinal surgery to assist

the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Performance of the QUARTEX™ Occipito-Cervico-Thoracic Spinal System was evaluated in accordance with ASTM F1717, ASTM F2706, and the "Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. A comparative analysis was provided for the Globus Navigation Instruments and its predicate device. Bacterial endotoxin testing was also provided.

Basis of Substantial Equivalence:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus Navigation Instruments have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The subject devices perform as well as or better than the predicate devices.



Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 18, 2021

Re: K211957

Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation
Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, KWP, OLO

Dated: June 23, 2021

Received: June 24, 2021

Dear Jennifer Antonacci:

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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

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K211957 - Jennifer Antonacci

Page 2

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,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211957

Device Name

QUARTEX™ Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211957

Device Name

Globus Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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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510(k) Summary: QUARTEX™ Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: August 17, 2021

Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Per 21 CFR §888.3075 Posterior Cervical Screw System
Product Code: NKG
Regulatory Class: II, Panel Code: 87

Per 21 CFR §888.3050 Spinal Interlaminar Fixation Orthosis
Product Code: KWP
Regulatory Class: II, Panel Code: 87

Globus Navigation Instruments
Per 21 CFR §882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II; Panel Code: 87

Primary Predicate: QUARTEX™ OCT Spinal System (K161591)

Addtl. Predicates: ELLIPSE® OCT Spinal System (K090565, K110963)
PROTEX® CT OCT Spinal System (K050391)

Reference Device: CREO® Stabilization System (K180210, K124058)

Purpose:
The purpose of this submission is to request clearance for additional QUARTEX™ implants and instruments.

Device Description:
The QUARTEX™ Occipito-Cervico-Thoracic Spinal System includes 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps, QUARTEX™ H-LINK™

integrated rod, and occipital plates and screws. The implants are composed of titanium alloy, stainless steel, or cobalt chromium molybdenum (CoCr) alloy.

QUARTEX™ constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX®, CREO®, REVERE®, or BEACON® Systems using corresponding connectors. The QUARTEX™ System includes manual surgical instruments.

Indications for Use:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Mechanical testing (static and dynamic compression bending and static interconnection testing) was conducted in accordance with ASTM F1717, ASTM F1798, and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was also conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:

Subject implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

Subject QUARTEX™ implants have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Globus Medical Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 16, 2017

Re: K171651
Trade/Device Name: EXCELSIUS GPS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 31, 2017
Received: August 1, 2017

Dear Dr. Kelly J. Baker:

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. 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.

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Page 2 - Kelly J. Baker, Ph.D.

K171651

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171651

Device Name

EXCELSIUS GPST™

Indications for Use (Describe)

The EXCELSIUS GPST™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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510(k) Summary: EXCELSIUS GPS™

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: June 1, 2017

Device Name: EXCELSIUS GPS™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Predicates: EXCELSIUS GPS™
Primary predicate: StealthStation (K133444)
Additional predicate: ROSA Spine (K151511)

EXCELSIUS GPS™ Instruments
Additional predicates:
CREO® (K143633)
REVERE® (K133350)
REVOLVE® (K111449)
QUARTEX™ (K161591)
ELLIPSE® (K123783)
SI-LOK® (K112028)
CAPTIVATE™ (K162825)

Purpose:
The purpose of this submission is to request clearance of EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments.

Device Description:
The EXCELSIUS GPS™ is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera. The navigation and guidance system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's

anatomy). Once this registration is created, the software displays the relative position of a tracked instrument, including the end effector of the robotic arm, on the patient images. This visualization can help guide the surgeon's planning and approach. As an aid to visualization, the surgeon can plan implant placement on the patient images prior to surgery. The information of the plan coupled with the registration provides the necessary information to provide visual assistance to the surgeon during free hand navigation or during automatic robotic alignment of the end effector. During surgery, the system tracks the position of GPS compatible instruments, including the end effector of the robotic arm, in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. Standard non-navigated metallic instruments that fit through the guide tube at the selected trajectory may be used without navigation while the guide tube is stationary, for uses such as bone preparation (e.g. rongeurs, reamers etc.) or placing implants (e.g. rod inserters, locking cap drivers) that are not related to screw placement. Navigation can also be performed without guidance. System software is responsible for all motion control functions, navigation functions, data storage, network connectivity, user management, case management, and safety functions. EXCELSIUS GPS™ surgical instruments are non-sterile, re-usable instruments that can be operated manually or with the use of the positioning system.

EXCELSIUS GPS™ instruments consist of registration instruments, patient reference instruments, surgical instruments, and end effectors. Registration instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification probe, surveillance marker, surgical instrument arrays, intra-op CT registration fixture, fluoroscopy registration fixture, and dynamic reference base (DRB). Patient reference instruments are either clamped or driven into any appropriate rigid anatomy that is considered safe and provides a point of rigid fixation for the DRB. Surgical instruments are used to prepare the implant site or implant the device, and include awls, drills, drivers, taps, and probes. End effectors are wirelessly powered guide tubes that attach to the distal end of the robotic arm and provide a rigid structure for insertion of surgical instruments.

Indications for Use:

The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

Technological Characteristics:

The EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments have similar technological characteristics to the predicate devices including the main system

components, workflow, user interface, software features, and design. The EXCELSIUS GPS™ System is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation. The table below provides a comparison of technological characteristics and principles of operation for the subject EXCELSIUS GPS™ and the predicate devices.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Principle of operation	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments - Guidance of instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative images - Patient registration - Surgical planning - Guidance of instruments
Input images	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D intra-operative exam
Integrated planning software	EXCELSIUS™ GPS Planning and Navigation Application software	Synergy Spine software	Rosanna Spine (Medtech)
Save/load planning	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes
Trajectory planning parameters	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter
Localization means	Optical system (infrared camera)	Optical (infrared camera) or electromagnetic system	Robot arm absolute encoders and optical system (infrared camera)
Image-guided	Yes	Yes	Yes
Controller	Force-controlled movement allowing robotic arm positioning	No controller; instruments are manually positioned by the surgeon.	Axis controller per joint Kinematic transformation Supervisor module
Patient registration method	Intra-op CT: Registration fixture Pre-op CT: Fluoroscopic to pre-op CT merge Fluoroscopy: Registration fixture	Point-to-point registration with anatomical markers Intra-op CT: Calibrated CT gantry to camera merge Pre-op CT: Point merge Fluoroscopy: Registration fixture	3D registration with X-Ray pattern containing radiopaque markers
Accuracy verification on anatomical landmarks	Yes (probe)	Yes (probe)	Yes (probe)
Real time display of instrument position	Yes	Yes	Yes

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Provide guide for instruments	Yes, instruments are used through the guide tube on the robotic arm or are manually positioned by the surgeon.	No, instruments are manually positioned by the surgeon.	Yes, instruments are mounted onto the robotic arm.
Patient fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is fixed to the patient's iliac crest or clamped on the spinous for tracking system	Reference is fixed to the patient's iliac crest for tracking system

Performance Testing:

Verification and validation testing was conducted on EXCELSIUS GPS™ to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation
- Surgical simulations conducted on phantom models
- Human cadaveric quantitative validation under clinically relevant scenarios
- Compliance conformity assessments per:
 - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
 - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance - Usability

Biocompatibility:

The biocompatibility evaluation for EXCELSIUS GPS™ has been conducted in accordance with ISO 10993 standards and blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", May 1, 1995 and FDA Guidance "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," June 16, 2016. The evaluation confirms that EXCELSIUS GPS meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:

Testing was performed to assure compliance with recognized safety standards: IEC 60601-1:2012 standard for electrical safety and IEC 60601-1-2:2014 standard for electromagnetic compatibility.

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained

in Medical Devices (May 11, 2005) and IEC 62304:2006-05 Medical Device Software – Software life cycle processes. The software for this device is considered a “MAJOR” level of concern.

Basis of Substantial Equivalence:

EXCELSIUS GPS™ has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.



July 10, 2020

Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K200047

Trade/Device Name: ExcelsiusGPS Cranial 1.0 Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: June 11, 2020
Received: June 12, 2020

Dear Jennifer Antonacci:

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.

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K200047 - Jennifer Antonacci

Page 2

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.

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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,

Adam D. Pierce -S
2020.07.10 17:31:58 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K200047

Device Name

ExcelsiusGPS Cranial 1.0 Module

Indications for Use (Describe)

The ExcelsiusGPS is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

510(k) Summary: ExcelsiusGPS Cranial 1.0 Module

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: July 10, 2020

Device Name: ExcelsiusGPS® Cranial 1.0 Module

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO, HAW
Regulatory Class: II

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Medtronic StealthStation S8 (K162309)
ROSA ONE Brain (K182417)

Purpose:

The purpose of this submission is to request clearance of the ExcelsiusGPS® Cranial 1.0 Module software and navigated instruments for access, preparation, and placement of cranial devices.

Device Description:

The ExcelsiusGPS® Cranial Module includes hardware and software that enables real time surgical navigation using radiological patient images (MRI, CT, and fluoroscopy), using a dynamic reference base and positioning camera. The navigation system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument on the patient images. As an aid to visualization, the surgeon can plan trajectories for instrument placement on the patient images prior to surgery. Registration provides the necessary information to provide visual assistance to the surgeon during freehand navigation. During surgery, the system tracks the position of GPS compatible instruments in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. System software is responsible for all

navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusGPS® surgical instruments include non-sterile, re-usable instruments and sterile instruments that are operated manually or with the use of the positioning system.

The ExcelsiusGPS® Cranial Module is designed to assist with stereotactic procedures that include guidance to cranial targets for instrument navigation and device placement. Instruments consist of end effector instruments, registration instruments, navigated instruments, patient positioning instruments, and surgical instruments. End effector instruments include instruments to connect to the Interchangeable Guide End Effector. Registration and navigated instruments incorporate unique array patterns with reflective markers, and are used to track patient anatomy and surgical instruments. Patient positioning instruments aid in patient fixation. Surgical instruments are used to access and prepare the local site and place devices, such as needles, electrodes, and tubes. The ExcelsiusGPS® Cranial Module is suitable for use in adult and pediatric patient populations in which the use of stereotactic neurosurgery may be appropriate.

Indications for Use:

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

Technological Characteristics:

The ExcelsiusGPS® Cranial Module and associated instruments have similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. The ExcelsiusGPS® Cranial Module is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
Principle of operation	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning	- Intraoperative/preoperative images - Patient registration - Surgical planning - Guidance of instruments

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
	- Guidance of instruments	- Guidance of instruments	- Real-time tracking of navigated instruments	
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software	Stealthstation Cranial	ROSANNA BRAIN
Save/load planning	Yes	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes	Yes
Image-guided	Yes	Yes	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Fluoroscopy: Registration Fixture Stereotactic Localizer Registration	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture	Point-to-point registration with anatomical markers or skin/bone fiducials Optical or electromagnetic trace merge Intra-Op CT: Calibrated CT gantry to camera merge Stereotactic Localizer Registration	Point-to-point registration with anatomical markers or skin/bone fiducials Stereotactic Localizer Registration Optical surface registration
Accuracy verification on anatomical landmarks	Yes	Yes	Yes	Yes
Real time display of instrument position	Yes	Yes	Yes	Yes
Patient fixation	Reference is attached to patient head holder Head is fixed to patient stabilization stand	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is attached to patient head holder	Head is fixed onto robot arm's flange

Performance Testing:

Verification and validation testing was conducted on ExcelsiusGPS® Cranial Module to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Surgical simulations conducted on phantom models - cranial sawbone models and registration matrix were used to quantify accuracy in a controlled setting
- Human cadaveric quantitative validation under clinically relevant scenarios - demonstrated system accuracy in navigating cranial devices to the desired location on patient images
- Compliance conformity assessments per:
 - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability
- Navigational accuracy of the subject device system with mean, standard deviation, and 99% confidence interval (CI). Results demonstrate the subject device meets the accuracy acceptance criteria for position and angle as follows:

Position		Angle	
Mean	99% CI	Mean	99% CI
< 1.5mm	≤ 2mm	< 2.0°	≤ 2°

Biocompatibility:

The biocompatibility evaluation for ExcelsiusGPS® has been conducted in accordance with FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process'," June 16, 2016. The evaluation confirms that ExcelsiusGPS® meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:

Testing was performed to assure compliance with recognized safety standard: IEC 60601-1:2012 standard for electrical safety. Electromagnetic compatibility was not affected.

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.

Basis of Substantial Equivalence:

ExcelsiusGPS® Cranial Module has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.



August 25, 2021

Globus Medical Inc.
Kelly Baker
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K211616
Trade/Device Name: ExcelsiusHub
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 25, 2021
Received: May 26, 2021

Dear Kelly Baker:

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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

K211616 - Kelly Baker

Page 2

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,

Jesse Muir -S

For: Shumaya Ali, M.P.H.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211616

Device Name

ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion 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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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) Summary: ExcelsiusHub™ System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: August 23, 2021

Device Name: ExcelsiusHub™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Excelsius3D™ Imaging System (K210912)

Purpose:

The purpose of this submission is to request clearance for the ExcelsiusHub™.

Device Description:

The ExcelsiusHub™ is a navigation system that includes hardware and software that enables real time surgical visualization using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), a dynamic reference base, and a camera tracking system. The navigation system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument on the patient images. This visualization can help guide the surgeon's planning and approach for implant placement. The patient's scan coupled with the registration provides visual assistance to the surgeon when using the system for free hand navigation. During surgery, the system tracks the position of compatible instruments in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. System software is responsible for all navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusHub™ uses the same instruments as ExcelsiusGPS®.

ExcelsiusHub™ may be used in conjunction with ExcelsiusGPS® for guidance of navigated instruments along a planned trajectory using a robotic arm. When connected to ExcelsiusGPS®, ExcelsiusHub™ software is responsible for both navigation and guidance.

Indications for Use:

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Technological Characteristics:

The ExcelsiusHub™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. ExcelsiusHub™ is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Principle of operation	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments - Guidance of instruments
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software
Save/load planning	Yes	Yes
Merge images functionality	Yes	Yes
Image-guided	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture

Device	Subject ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Accuracy verification	Yes	Yes
Real time display of instrument position	Yes	Yes
Patient fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system

*Excelsius3D 510(k) under FDA review (remove *s and this note upon clearance)

Performance Testing:

Verification and validation testing were conducted on ExcelsiusHub™ to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Surgical simulations conducted on phantom models
- Qualitative validation to confirm intended use
- Electrical Safety and Electromagnetic Compatibility
 - Testing was performed to assure compliance with recognized safety standards for electrical safety and electromagnetic compatibility
 - IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
 - IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: *Electromagnetic disturbances*
 - IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: *Usability*
 - IEC 62304:2015 Medical device software - Software lifecycle processes
 - IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.

Basis of Substantial Equivalence:

ExcelsiusHub™ has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use.

The information provided within this premarket notification supports substantial equivalence to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

January 30, 2015

Globus Medical, Incorporated
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K143633

Trade/Device Name: CREO® Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: January 5, 2015
Received: January 6, 2015

Dear Dr. Baker:

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. 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 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); good manufacturing practice requirements as set

Page 2 – Kelly J. Baker, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K143633

Device Name

CREO® Stabilization System

Indications for Use (Describe)

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO® 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO® Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

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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PRASStaff@fda.hhs.gov

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510(k) Summary: CREO® Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: January 30, 2015

Device Name: CREO® Stabilization System

Classification: Per 21 CFR as follows:
§888.3070* Spondylolisthesis Spinal Fixation Device System
System
§888.3070 Pedicle Screw Spinal System, Adolescent
Idiopathic Scoliosis
§888.3070 Pedicle Screw Spinal System
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Codes NKB*, OSH, MNH, MNI, KWQ, KWP
Regulatory Class III* and II, Panel Code 87.
**Primary*

Primary Predicate: CREO® Stabilization System (K124058)

Purpose:

The purpose of this submission is to request clearance for additional cobalt chrome implants for the CREO® Stabilization System.

Device Description:

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO® implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO® Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

CREO® implants are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

Indications for Use:

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO® 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion

(pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/iliac.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO® Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Technological Characteristics:

The technological characteristics of the CREO® Stabilization System additional implants are similar to the predicate device in terms of design, dimensions, intended use, materials, and performance characteristics.

Performance Data:

Engineering analysis and mechanical testing (static and dynamic compression and static torsion) conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004, were provided in support of substantial equivalence.

Basis of Substantial Equivalence:

CREO® additional implants are similar to the predicate device with respect to technical characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device. CREO® additional implants perform as well as or better than the predicate device.

510(k) Summary: CREO™ Stabilization System

MAY 13 2013

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: May 3, 2013

Device Name: CREO™ Stabilization System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
§888.3070 Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
Product Codes MNH, MNI, KWQ, KWP, NKB, OSH
Regulatory Class II and III, Panel Code 87.

Predicate(s): REVERE® Stabilization System K122226
REVERE® 4.5 Stabilization System K113395
Medtronic CD Horizon® Spinal System K102807
Synthes USS (including Matrix and Click'X) Spinal System.
K031175, K100952 & K103287
DePuy VIPER® 2 System K111136

Purpose:

The purpose of this submission is to request clearance of the CREO™ Stabilization System.

Device Description:

The CREO™ Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO™ implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO™ Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. All other CREO™ implants are composed of titanium alloy or stainless steel, as specified in ASTM F136, F1295, F67 and F138. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

Indications for Use:

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO™ 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/iliac.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO™ Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO™ Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Performance Data:

Mechanical testing (static and dynamic compression, and static torsion) was conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Conclusions / Basis of Substantial Equivalence:

The CREO™ Stabilization System implants are similar to the predicate implants with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. CREO™ implants are as safe, as effective, and perform as well as or better than the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Incorporated
% Ms. Sarah M. Fitzgerald
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Letter dated: May 13, 2013

Re: K124058
Trade/Device Name: CREO™ Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: April 19, 2013
Received: April 22, 2013

Dear Ms. Fitzgerald:

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. 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 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); good manufacturing practice requirements as set

Page 2 – Ms. Sarah M. Fitzgerald

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement510(k) Number: K124058Device Name: CREO™ Stabilization System**INDICATIONS:**

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO™ 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO™ Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO™ Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K124058

Attachment D: Recognized Consensus Standards

The QUARTEX devices described in this premarket notification conform with the requirements of the FDA recognized consensus standards listed in **Table 1**.

Table 1: FDA Recognized Standards

FDA Recognition Number	Standard Number	Standard Organization	Standard Title
(b)(4)			
14-501	F1886/F1886M-16	ASTM	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection
11-388	F1717-21	ASTM	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
14-511	ST79:2017	AAMI / ANSI	Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
14-409	11137-2:2013	AAMI / ANSI / ISO	Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
14-530	11607-1 Second Edition 2019-02	ISO	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging
14-333	17665-1:2006/(R)2013	ANSI / AAMI / ISO	Sterilization Of Health Care Products -- Moist Heat -- Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices
2-258	10993-1 Fifth Edition 2018-08	ISO	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

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Mechanical Testing Reports

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Design Verification Procedure, QUARTEX Instrumentation Integration

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Rev

Approvals

Legend: Y = Required, N = Not required, ? = As needed

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Confidential

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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) #: K231850 Date Received by DCC: Jun 23, 2023

Lead Reviewer: Michael Molyneaux-Francis

Center: CDRH Office: OHT 6 Division: DHT6B

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:

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. <i>Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> 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. <i>Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☐	☐	☒
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.

*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. <i>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...).</i>	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	

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.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
*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	☒	☐			III
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			III
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).	☒	☐		☐	II
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	III
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).	☒	☐		☐	I
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
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.	☒	☐		☐	III
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.	☒		☐	☐	Att. D
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
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.	☒	☐			Att. D

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
*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 #
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).	☒	☐		☐	X
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.	☒	☐			X
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.	☒	☐	☐		X/Att. B +
c) A list and description of each device for which clearance is requested.	☒	☐	☐		Att. H
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).	☒	☐			Att. H
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.	☒	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
*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) 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. <i>Information regarding <u>documenting preamendment status</u> is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i>	☒	☐			III
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)] <i>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.</i>				☐	
a) Indications for Use	☒	☐			XI
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			XI
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).	☒	☐		☐	Att. B
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 801.19).	☒	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
*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 #
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 <u>21 CFR 809.10</u> .	☐	☐	☒	☐	
E. Sterilization					
If an <i>in vitro</i> 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)					
☐ 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. <i>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.</i>					
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.	☒	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
*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 #
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☒	☐	☐		Att. A
c) Identification of device, and/or accessories, if applicable, that are reusable.	☒	☐	☐		III/Att. E +
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).	☒	☐			XIII
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 amoebocyte lysate [LAL]).	☐	☐	☒		Att. A
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.	☒	☐	☐		Att. B
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		Att. B
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		Att. B
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.	☒		☐	☐	
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.	☒	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
	Yes	No	N/A	Comment	*Page #
*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.					
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	☒	☐	☐	☐	Att. A
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 than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☐	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
	Yes	No	N/A	Comment	*Page #
*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.					
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-testing-within-a-risk-management-process \"), 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).	☒	☐		☐	X
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 or comments: Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024						Yes	No	N/A	Comment	*Page #
*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.										
J. Electrical Safety and EMC										
Electrical Safety Submission states that the device: <i>(one of the below must be checked)</i>							☐		☐	
☐ 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: <i>(one of the below must be checked)</i>							☐		☐	
☐ 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 .						☒	☐	☐	☐	Att. E
a) Submission includes an explanation of how the data generated from each test 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. Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024					
	Yes	No	N/A	Comment	*Page #
*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.					
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.	☒		☐	☐	
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:			☒		
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.					

Digital Signature Concurrence Table

Records processed under FOIA Request 2024-3481; Released by CDRH on 10-14-2024

Reviewer Sign-Off
(digital signature
required)

Michael S.
Molyneaux-francis -
S

Digitally signed by Michael
S. Molyneaux-francis -S
Date: 2023.07.05 09:41:11
-04'00'

Management Sign-Off
(digital signature
required)

Management review of checklist and concurrence with the decision is required.

Hello Jennifer,

Thank you for agreeing to speak with us today. I have confirmed receipt of your redlined and clean copies. I will review this information accordingly and get back to you if we have further questions.

Have a great evening,

Michael

Michael Molyneaux-Francis

General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team

CDRH / OPEQ / OHT6 / DHT6B

[U.S. Food and Drug Administration]<<http://www.fda.gov/>>

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From: Jennifer Antonacci (b)(6)

Sent: Wednesday, March 13, 2024 5:38 PM

To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Subject: [EXTERNAL] RE: K231850/S001 - Interactive Requests

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.

Hi Michael,

Thank you again for today's call. I appreciate you and Colin taking the time to meet with me to discuss your questions. Please see attached for a revised 510(k) Summary,

(b)(4)

Please let me know if you have any further questions.

Kind regards,

Jennifer

[cid:image004.png@01DA7576.A684C240]<http://secure-web.cisco.com/1mnRYCUfIheGPHWMaiJ-GNHBuA54LH0YGc8VM4kzaM5uEds7pvsoatbjsOG5AjUEXkddpwZxxdcp9LG6Etwo4SF96NNr6h34woBOFFehte7AhF7Bq1AeXUfBJ-SS2MZRIgu9yFAOI1ejMVJ57frV4J_016H75bSZzZxSAygd7PRU_vFooMCwiQw6MFCWKEvL2BIpdfGCY811UX1kMlbIa9A/http%3A%2F%2Fwww.globusmedical.com%2F>

Jennifer Antonacci

, Ph.D.

Senior Group Manager, Regulatory Affairs

Phone: 610-930-1800 ext (b)(6)

Fax: 610-930-2042<fax:610-930-2042>

Globus Medical, Inc.

2560 General Armistead Ave. Audubon, PA 19403

[cid:image006.png@01DA7576.A684C240]<<https://www.linkedin.com/company/globus-medical>>

[cid:image007.png@01DA7576.A684C240]<<https://www.instagram.com/globusmedicalinc/?hl=en>>

[cid:image008.png@01DA7576.A684C240]<<https://www.facebook.com/GlobusMedical/>>

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>>

Sent: Wednesday, March 13, 2024 1:42 PM

To: Jennifer Antonacci

(b)(6)

Subject: [External Sender] RE: K231850/S001 - Interactive Requests

Hello Jennifer,

Would you be available for a quick call between 3:00pm to 3:30pm today?

Thank you,

Michael

Michael Molyneaux-Francis

General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team

CDRH / OPEQ / OHT6 / DHT6B

[U.S. Food and Drug Administration]<<https://url.us.m.mimecastprotect.com/s/0i46CxxkzkgTBzYoDs8iM7Y/>>

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From: Molyneaux-Francis, Michael

Sent: Wednesday, March 13, 2024 1:11 PM

To: Jennifer Antonacci

(b)(6)

Subject: RE: K231850/S001 - Interactive Requests

Hello Jennifer,

As usual, thank you for your quick actions. I will review with my team and get back to you if there are any further issues.

Thank you,

Michael

Michael Molyneaux-Francis

General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team

CDRH / OPEQ / OHT6 / DHT6B

[U.S. Food and Drug Administration]<<https://url.us.m.mimecastprotect.com/s/0i46CxxkzkgkBzYoDs8iM7Y/>>

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From: Jennifer Antonacci

(b)(6)

Sent: Wednesday, March 13, 2024 12:57 PM

To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov><mailto:Michael.Molyneaux-Francis@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K231850/S001 - Interactive Requests

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.

Hi Michael,

Thank you for your email. Please see attached for our responses to your March 12th interactive questions.

(b)(4)

Please let me know if you have any further questions or would like to discuss anything directly on a call.

Kind regards,

Jennifer

[cid:image016.png@01DA7576.A684C240]<http://secure-web.cisco.com/11BRw6rhoiTDwQQ0N2mXAkHfhcYwvIC_k4HTZCiR7L7nconjfTzPUjeE2KaDYRZMkyy_kyqAWpQgSH6J_qRUabNQPaR1ylIvg7lD4DzAwIlCmUy-9pMotoSp_u73kln3WJO-wfTmPz4J7FUDEnDnmRXw1ya9v309FAsSNfuklEkwiZucKgWE_HufNIb8bUVn0ouzgdUFmWA6wvKLrudILX7w/http%3A%2F%2Fwww.globusmedical.com%2F>

Jennifer Antonacci

, Ph.D.

Senior Group Manager, Regulatory Affairs

Phone: 610-930-2042

(b)(6)

Fax: 610-930-2042

Globus Medical, Inc.

2560 General Armistead Ave. Audubon, PA 19403

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[cid:image007.png@01DA7576.A684C240]<https://www.instagram.com/globusmedicalinc/?hl=en>

[cid:image008.png@01DA7576.A684C240]<https://url.us.m.mimecastprotect.com/s/W-QfCDkZkvtMy4lwSkBokX/>

[cid:image009.png@01DA7576.A684C240]<https://www.youtube.com/@GlobusMedical>

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>

Sent: Tuesday, March 12, 2024 3:26 PM

To: Jennifer Antonacci

(b)(6)

Subject: [External Sender] K231850/S001 - Interactive Requests

Importance: High

Hello Jennifer,

I have come across several issues pertaining to

(b)(4)

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Let me know if this date is not acceptable. The interactive requests are as follows:

(b)(4)

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Please reach out if you seek additional information or have further questions. I will let you know if further issues arise.

Respectfully,

Michael

Michael Molyneaux-Francis, FE

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

General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Tel: 240-402-5178

Michael.Molyneaux-Francis@fda.hhs.gov<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>

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Administration]<<https://url.us.m.mimecastprotect.com/s/DslqCJ6K6BUyVNElikR6ZY/>>

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February 9, 2024

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
Attn: Michael Molyneaux-Francis

Re: K231850/S1 QUARTEX Additional Implants

Dear Mr. Molyneaux-Francis,

This submission is in response to the deficiency letter dated August 21, 2023 requesting additional information. The original questions are identified in bold font, and the responses are identified in standard font. An eCopy is enclosed.

Globus believes that the information provided in this response is sufficient to address the deficiencies. Please feel free to contact me at (610) 930-1800 (b)(6) or by email at (b)(6)

Sincerely,

(b)(6)

Senior Group Manager, Regulatory Affairs
Globus Medical, Inc.

Enclosed:
K231850/S1 eCopy

K231850 Response to FDA Request for Additional Information 8/21/2022

The original questions are identified in bold, and the responses in standard font.

MAJOR DEFICIENCY LIST

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	GPS QUARTEX MIS Quantitative Validation Summary	Document No.	(b)(4)
		Rev. No.	(b)(4)
		Page No.	See Footer

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QUARTEX MIS Quantitative Validation Summary

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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Michael.Molyneaux-Francis@fda.hhs.gov)

FOLDER: K231850 - 392 pages

COMPANY: ()

PRODUCT: ()

SUMMARY:

DATE REQUESTED: Jun 30, 2023

DATE PRINTED: Jun 30, 2023

Note: Printed





U.S. Department of Health & Human Services

Food and Drug Administration

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June 22, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

JUN 23 2023

RECEIVED

Re: QUARTEX Additional Implants Premarket Notification

K231850

Dear Sir/Madam,

Globus Medical Inc. hereby submits this **Traditional 510(k)** to request clearance for **QUARTEX Additional Implants**, which are line extensions to the previously cleared QUARTEX Occipito-Cervico-Thoracic Spinal System, as well as additional instruments for use with ExcelsiusGPS or ExcelsiusHub. These devices are considered Class II under panel code 87 which is with the same classification regulation as the predicate devices. In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, this submission constitutes a Premarket Notification for QUARTEX Additional Implants. There have been no prior submissions for this device. An eCopy is enclosed. A draft Refuse to Accept checklist is included for convenience.

Documentation is provided to support a claim of substantial equivalence to commercially available predicate devices, including the QUARTEX system. The intent to market this device and the information contained in this submission are considered proprietary, confidential, and protected from public disclosure in accordance with the provisions for confidentiality under 21 CFR §807.95 and other applicable provisions of the law.

Globus believes that the information contained in this submission is sufficient for the agency to find that the subject implants are substantially equivalent to the predicate devices. If additional information is required, please contact me at (610) 930-1800 (b)(6) or by email at (b)(6). An alternate contact, Kelly Baker, PhD, Senior Vice President of Regulatory and Clinical Affairs, may be reached at (610) 930-1800 (b)(6) or by email at (b)(6).

Sincerely,

(b)(6)

Benjamin Antonacci, PhD
Group Manager, Regulatory Affairs
Globus Medical, Inc.

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) GLOBUS MEDICAL INC Globus Medical Inc. Valley Forge Business Center 2560 General Armistead Ave. Audubon PA 19403 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4954	2. CONTACT NAME Kelly Baker 2.1 E-MAIL ADDRESS (b)(6) 2.2 TELEPHONE NUMBER (include Area code) 610-930-1800 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 610-415-5322
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 <u>Select an application type:</u>	
☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request	3.1 Select a center ☒ CDRH ☐ CBER <u>3.2 Select one of the types below</u> ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 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 ☒ 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? ☒ 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 ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ 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 ☒ NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@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)

25-Apr-2023

Form FDA 3601 (07/22)

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June 22, 2023

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Center for Devices and Radiological Health
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10903 New Hampshire Avenue
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Re: QUARTEX Additional Implants Premarket Notification

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Documentation is provided to support a claim of substantial equivalence to commercially available predicate devices, including the QUARTEX system. The intent to market this device and the information contained in this submission are considered proprietary, confidential, and protected from public disclosure in accordance with the provisions for confidentiality under 21 CFR §807.95 and other applicable provisions of the law.

Globus believes that the information contained in this submission is sufficient for the agency to find that the subject implants are substantially equivalent to the predicate devices. If additional information is required, please contact me at (610) 930-1800 (b)(6) 1 or by email at (b)(6). An alternate contact, Kelly Baker, PhD, Senior Vice President of Regulatory and Clinical Affairs, may be reached at (610) 930-1800 (b)(6) or by email at (b)(6).

Sincerely,

(b)(6)

Group Manager, Regulatory Affairs
Globus Medical, Inc.

*Contains Nonbinding Recommendations***Appendix A. Acceptance Checklist for Traditional 510(k)s****(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 application.

510(k)#:**Date Received by DCC:****510(k) Lead Reviewer:****Center:****Office:****Division:****Decision:** Accept _____ Refuse to Accept _____**If Accept, notify the submitter.****If Refuse to Accept, notify submitter electronically and include a copy of this checklist.****Is an Addendum attached?: Yes No**

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.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified 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. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☒	☐	

Contains Nonbinding Recommendations

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 the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			
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. <i>Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> 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. <i>Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☐	☐	☒
Comments:			

Contains Nonbinding Recommendations

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 division 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

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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 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.

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.	☒	☐	1
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. <i>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...).</i>	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	
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.

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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.		Yes	No	N/A	*Page #												
*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.																	
A.	Administrative																
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐														
	Comments:																
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)): <table border="1"> <tr> <td>a.</td> <td>Device trade/proprietary name</td> <td>☒</td> <td>☐</td> <td></td> <td>6</td> </tr> <tr> <td>b.</td> <td>Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion</td> <td>☒</td> <td>☐</td> <td></td> <td>6,9</td> </tr> </table>	a.	Device trade/proprietary name	☒	☐		6	b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐		6,9				
a.	Device trade/proprietary name	☒	☐		6												
b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐		6,9												
	Comments: <i>see cover letter, 510(k) summary, section VI</i>																
3.	Submission contains an Indications 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). <i>See recommended format</i> (https://www.fda.gov/media/86323/download).	☒	☐		2-5												
	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.	☒	☐														
	Comments: <i>see section III</i>																

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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.		Yes	No	N/A	*Page #
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l). <i>See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).</i>	☒	☐		1
Comments:					
6.	Submission is a class III 510(k) Device. <i>Select "N/A" only if submission is not a class III 510(k).</i>	☐		☒	
a.	Contains class III Summary and Certification per 21 CFR 807.87(k). <i>See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).</i>	☐	☐	☒	
Comments:					
7.	Submission contains clinical data. <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.</i>	☐		☒	
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. <i>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.</i>	☐	☐	☒	

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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	*Page #
		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. <i>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).</i>	☐	☐	☒	
		c.	Statements of Compliance for Clinical Investigations <i>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.</i> <i>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.</i> <i>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>	☐		☒	

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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	*Page #
		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 it was not subject to the regulations under 21 CFR 56.104 or 56.105). <u>OR</u> The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. <i>Select "N/A" if the clinical investigations were conducted solely OUS.</i>	☐	☐	☒	
		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). <u>OR</u> The submission includes a waiver request in accordance with 21 CFR 812.28(c). <u>OR</u> 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. <i>Select "N/A" if the clinical investigations were conducted solely inside the US.</i>	☐	☐	☒	
Comments:							

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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	*Page #
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. <i>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, available at https://www.fda.gov/media/72421/download). 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).</i>	☒	☐		
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. <i>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.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	☒	
Comments: <i>See Cover Letter</i>					
9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). <i>This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.</i>	☒		☐	
a.	The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐	<i>Att. D</i>

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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	*Page #
		i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," 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 "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," 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).	☐		☒	
		i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
Comments:							
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.						☒	
	10.	Submission identifies the product as a combination product.		☐	☐		
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.		☐		☐	

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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	*Page #
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐		
			Comments:				
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. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☒		☐	
		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. <i>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.</i>	☒	☐	☐	11-27

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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.		Yes	No	N/A	*Page #
*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.					
	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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	11-27
	Comments: <i>See Section X</i>				
	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).	☒	☐		11-27
	Comments:				
	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.	☒	☐		11-27
	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.	☒	☐		11-27
	c. A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>	☒	☐	☐	11-27

Contains Nonbinding Recommendations

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 #
	d. Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. <u>OR</u> 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). <i>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.</i>	☒	☐		11-27
	Comments: See Section X, Att. H				
15.	Device is intended to be marketed with accessories and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>	☒		☐	Att. H
	a. Submission includes a list of all accessories to be marketed with the subject device.	☒	☐		Att. H
	b. Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. <i>Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	☒	☐	☐	Att. H
	c. A 510(k) number is provided for each accessory that received a prior 510(k) clearance. <u>AND</u> A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐		Att. H
	Comments: See Att. H				

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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	*Page #
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. <i>Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i>	☒	☐		6
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.	☒	☐		
	Comments: <i>See 510(k) Summary d Section x</i>				
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)]. <i>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.</i>				

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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	*Page #
	a.	Indications for use <i>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.</i>	☒	☐		11
	b.	Technology, including technical specifications, features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the 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.</i>	☒	☐		16, 26
		Comments:				
D.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)					
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		Att. B
	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).	☒	☐		Att. B
	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. B

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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	*Page #
	Comments:				
19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		Att. B.
	Comments: <i>See Attachment B</i>				
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, " <u>Use of Symbols in Labeling</u> " (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). <i>Select "N/A" if not indicated for prescription use.</i>	☒	☐	☐	Att. B
	Comments: <i>See Attachment B</i>				
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. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☒		☐	Att. B
	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. <i>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.</i>	☒	☐	☐	Att. B

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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	*Page #
	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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	
	Comments:				
	22. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>	☐	☐	☒	
	Comment:				
E.	Sterilization <i>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.</i>			☐	

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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.		Yes	No	N/A	*Page #
*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. Submission states that the device and/or accessories, if applicable, are: (<i>one of the below must be checked</i>) ☒ 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. <i>If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."</i> <i>The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:</i> <i>Supplied sterile and requires reprocessing prior to subsequent patient use</i> <i>Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use</i> <i>Reusable medical device (single-user) reprocessed between each use</i> <i>Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use</i> <i>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.</i>		☐			Att-A
Comments: <i>See Attachment A</i>					
23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
	a. Identification of device and/or accessories, if applicable, that are provided sterile. <i>Select "N/A" if no part of the device or accessories are provided sterile.</i>	☒	☐	☐	Att-A + Att-H
	b. Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. <i>Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.</i>	☒	☐	☐	Att-A + Att-H
	c. Identification of device and/or accessories, if applicable, that are reusable. <i>Select "N/A" if no part of the device or accessories, are reusable.</i>	☐	☐	☐	
	Comments: <i>See Attachment A & Attachment H</i>				
24.	If the device and/or accessories, if applicable, are provided sterile: <i>Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.</i>			☐	
	a. Sterilization method is stated for each device (including dose for radiation sterilization)	☒	☐		Att-A
	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). <i>Note: the sterilization validation report is not required.</i>	☒	☐		Att-A
	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. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	☐	☐	☒	
	d. Sterility Assurance Level (SAL) stated	☒	☐		Att-A
	e. Submission includes description of packaging	☒	☐		Att-A

Contains Nonbinding Recommendations

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 #
	f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amoebocyte lysate [LAL]). <i>Select "N/A" if not labeled "non-pyrogenic."</i>	☐	☐	☒	
		Comments:				
25.		If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: <i>Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.</i>			☐	
	a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.</i>	☒	☐	☐	Att. A + Att. B
	b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.</i>	☒	☐	☐	Att. A + Att. B
	c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.</i>	☒	☐	☐	Att. A + Att. B

Contains Nonbinding Recommendations

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 #
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "<u>Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications</u>" (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). <i>Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐		☒	
		i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. <i>Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐	☐	☐	
		Comments: <i>See Attachment A & Attachment B</i>					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☒		☐	

Contains Nonbinding Recommendations

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.	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. <i>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.</i>	☒	☐	☐	Att. A + Att. B
	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. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☒	☐	☐	Att. A + Att. B
		Comments: See Attachment A + Attachment B				
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.	☒	☐		Att. A

Contains Nonbinding Recommendations

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 #
	Comments: <i>see Attachment A</i>				
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. <i>Select "N/A" if the device is not provided sterile.</i>	☐	☒	☐	<i>Att. A</i>
	Comments: <i>see Attachment A</i>				
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.	☒	☐	☐	<i>Att. A</i>
	Comments: <i>see Attachment A.</i>				
G.	Biocompatibility <i>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.</i>			☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*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. Submission states that there: <i>(one of the below must be checked)</i> ☒ 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 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>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 tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."</i> <i>An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.</i>			☐		28-33
Comments: <i>See Section X</i>					
30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		28-33
Comments: <i>See Section X</i>					
31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☒	☐		28-33
Comments: <i>See Section X</i>					

Contains Nonbinding Recommendations

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 #
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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" 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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" 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 "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" 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).	☒	☐		28-33
	Comments:				
H.	Software				

Contains Nonbinding Recommendations

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 states that the device: <i>(one of the below must be checked)</i> ☐ Does contain software/firmware ☒ 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. <i>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."</i>			☐		9
Comments:					
33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
Comments:					
34.	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," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-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). <i>Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.</i>	☐	☐		

Contains Nonbinding Recommendations

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 #
Comments:					
I.	Cybersecurity				
	Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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. <i>If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."</i>	☐		9	
	35. All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. OR 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).	☐	☐		
Comments:					
J.	Electrical Safety and EMC				

Contains Nonbinding Recommendations

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 #
	Electrical Safety: Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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 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. <i>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."</i>		☐		9
36.	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:				

Contains Nonbinding Recommendations

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 #
EMC: Submission states that the device: <i>(one of the below must be checked)</i> ☐ 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 This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>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."</i>			☐		9
Comments:					
37.	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:					

Contains Nonbinding Recommendations

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 #
K.	Performance Data General <i>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 L.</i>			☐	
Comments:					
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. Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.	☒	☐	☐	Att E + 34-36
a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). Select "N/A" if the submission does not include performance data.	☒	☐	☐	Att E 34-36
Comments: See section X and Attachment E					

Contains Nonbinding Recommendations

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 #
39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☒		☐	
a.	The submission addresses performance data 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. <i>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.</i>	☒	☐	☐	Att-E
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. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls 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.</i>	☒	☐	☐	Att-E
Comments:					

Contains Nonbinding Recommendations

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 #
40.	If literature is referenced in the submission, submission includes: <i>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.</i> <i>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.</i>				☒	
	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:					
41.	For each completed animal study, the submission provides the following: <i>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.</i>				☒	
	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:					

Contains Nonbinding Recommendations

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 #
L.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))				
	Submission indicates that device: <i>(one of the below must be checked)</i> ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>				9
42.	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:				
43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐	☐	☐	

Contains Nonbinding Recommendations

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.	The submission addresses performance data 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. <i>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.</i>	☐	☐	☐	
		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. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification 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.</i>	☐	☐	☐	
		Comments:					

Contains Nonbinding Recommendations

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

Globus Medical 510(k) Premarket Notification

QUARTEX Additional Implants

TRADITIONAL 510(k)

Submitted to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted by:

Globus Medical, Inc.
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Jennifer Antonacci, Ph.D.

(b)(6)

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Kelly J. Baker, Ph.D.

(b)(6)

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I. Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required By 21 CFR §807.87(k)]

I, Jennifer Antonacci, Ph.D., certify that, in my capacity as Group Manager, Regulatory Affairs, of Globus Medical, Inc., 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)

Premarket Notification [510(k)] Number

Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

II. Indications for Use

The Indications for Use Statements (Form 3881) are provided on the following pages and are suitable for publication on the FDA website.

III. 510(k) Summary

The 510(k) Summary is provided on page 6 and is suitable for publication on the FDA website.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

QUARTEX® Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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.

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name
ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion 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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510(k) Summary: QUARTEX® Additional Implants

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X. Description of the Device

Overview

The **predicate QUARTEX Occipito-Cervico-Thoracic (OCT) System** (K161591, K211957) is a posterior cervical stabilization system for use in the OCT spine (occiput-T3). Implants include polyaxial screws, polyaxial shoulder screws, hooks, locking caps, (b)(4), and various specialized connectors (**Figure 1**). QUARTEX screws are cleared for use with ExcelsiusGPS using navigated instruments. The implants may be connected to larger diameter rods using connectors. QUARTEX implants are manufactured from titanium (Ti) alloy, stainless steel, or cobalt chromium molybdenum (CoCr) alloy.

The **reference CREO Stabilization System**, including CREO 4.75, MIS, Threaded and AMP (K143633, K124058) is a modular thoracolumbar stabilization system that includes (b)(4) a variety of polyaxial and monoaxial screws (**Figure 2**), and connectors that secure two rods or extend a rod. Rods are available in titanium alloy, stainless steel, or CoCr alloy. CREO screws are cleared for use with ExcelsiusGPS using navigated instruments.

The **subject QUARTEX implants** are additional screws and rods that may be used with previously cleared QUARTEX implants, and include (b)(4) smaller diameter (b)(4) polyaxial screws and (b)(4) (b)(4) and MIS rods (**Figure 3**). Implants may be connected to larger diameter rods using cleared connectors. Instruments for placing and reducing new MIS rods and for navigating implants with ExcelsiusGPS are included. Subject screws are manufactured from Ti alloy, and the MIS rods are manufactured from Ti alloy, stainless steel, or CoCr alloy. Subject QUARTEX implants have the same indications for use as the predicate QUARTEX system.

(b)(4)

Figure 1. Predicate QUARTEX implants and full construct.

(b)(4)

Figure 2. Reference CREO screws and rods (examples).

(b)(4)

Figure 3. Subject QUARTEX screws and rods.

A complete list of components and confidential engineering drawings of the subject devices are provided in **Attachment H**. The draft QUARTEX surgical technique manual and draft ExcelsiusGPS User Manual Supplement are provided in **Attachment B**.

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Attachment C: Commercially Available Device Information

The SE Letters and 510(k) Summaries for the following commercially available devices are included in this attachment:

Primary Predicate

- QUARTEX Occipito-Cervico-Thoracic (OCT) System (K161591)

Additional Predicates

- QUARTEX OCT System (K211957)
- ExcelsiusGPS (K171651, K200047)
- ExcelsiusHub (K210606)

Reference Device

- CREO Stabilization System (K143633, K124058)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

September 21, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K161591

Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Regulatory Class: Unclassified

Product Code: NKG, KWP, OLO

Dated: September 7, 2016

Received: September 8, 2016

Dear Dr. Baker:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Kelly J. Baker, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K161591

Device Name

QUARTEX™ Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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 AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

K161591

Device Name

Globus Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX, CREO, REVERE, REVOLVE, ELLIPSE, and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary: QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus Navigation Instruments

Company: Globus Medical, Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: September 15, 2016

Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Pre-Amendment Device
Cervical Pedicle Screw Spinal Fixation Orthosis
Product Code: NKG
Regulatory Class: Unclassified

Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
Product Code: KWP
Regulatory Class: II, Panel Code: 87

Globus Navigation Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II; Panel Code: 87

Predicates: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Primary predicate: ELLIPSE® OCT Spinal System (K150552)
Additional predicates: Synapse OCT System (K142838)
Reference: H-LINK™ Integrated Rod (K073517)
PROTEX CT® (K050391)

Globus Navigation Instruments
Additional predicate: Globus Navigation Instruments (K153203)

Purpose:

The purpose of this submission is to request clearance for QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants and instruments, and Globus Navigation instruments for use with the Medtronic StealthStation® System.

Device Description:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System consists of 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps, QUARTEX™ H-LINK™ Integrated Rod and occipital plates. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537).

QUARTEX™ constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX®, CREO®, REVERE®, or BEACON® Systems using corresponding connectors.

The QUARTEX™ System include manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Globus Navigation Instruments are nonsterile, reusable instruments that can be operated manually and are intended to be used with the Medtronic StealthStation® System.

Indications for Use:**QUARTEX™ Occipito-Cervico-Thoracic Spinal System**

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX, CREO, REVERE, REVOLVE, ELLIPSE, and PROTEX CT Stabilization Systems) during spinal surgery to assist

the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Performance of the QUARTEX™ Occipito-Cervico-Thoracic Spinal System was evaluated in accordance with ASTM F1717, ASTM F2706, and the "Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. A comparative analysis was provided for the Globus Navigation Instruments and its predicate device. Bacterial endotoxin testing was also provided.

Basis of Substantial Equivalence:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus Navigation Instruments have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The subject devices perform as well as or better than the predicate devices.



Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 18, 2021

Re: K211957

Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation
Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, KWP, OLO

Dated: June 23, 2021

Received: June 24, 2021

Dear Jennifer Antonacci:

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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

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10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

K211957 - Jennifer Antonacci

Page 2

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,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211957

Device Name

QUARTEX™ Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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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Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211957

Device Name

Globus Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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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510(k) Summary: QUARTEX™ Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: August 17, 2021

Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Per 21 CFR §888.3075 Posterior Cervical Screw System
Product Code: NKG
Regulatory Class: II, Panel Code: 87

Per 21 CFR §888.3050 Spinal Interlaminar Fixation Orthosis
Product Code: KWP
Regulatory Class: II, Panel Code: 87

Globus Navigation Instruments
Per 21 CFR §882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II; Panel Code: 87

Primary Predicate: QUARTEX™ OCT Spinal System (K161591)

Addtl. Predicates: ELLIPSE® OCT Spinal System (K090565, K110963)
PROTEX® CT OCT Spinal System (K050391)

Reference Device: CREO® Stabilization System (K180210, K124058)

Purpose:
The purpose of this submission is to request clearance for additional QUARTEX™ implants and instruments.

Device Description:
The QUARTEX™ Occipito-Cervico-Thoracic Spinal System includes 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps, QUARTEX™ H-LINK™

integrated rod, and occipital plates and screws. The implants are composed of titanium alloy, stainless steel, or cobalt chromium molybdenum (CoCr) alloy.

QUARTEX™ constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX®, CREO®, REVERE®, or BEACON® Systems using corresponding connectors. The QUARTEX™ System includes manual surgical instruments.

Indications for Use:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Mechanical testing (static and dynamic compression bending and static interconnection testing) was conducted in accordance with ASTM F1717, ASTM F1798, and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was also conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:

Subject implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

Subject QUARTEX™ implants have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Globus Medical Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 16, 2017

Re: K171651
Trade/Device Name: EXCELSIUS GPS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 31, 2017
Received: August 1, 2017

Dear Dr. Kelly J. Baker:

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. 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 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-

Page 2 - Kelly J. Baker, Ph.D.

K171651

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171651

Device Name

EXCELSIUS GPST™

Indications for Use (Describe)

The EXCELSIUS GPST™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

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)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

510(k) Summary: EXCELSIUS GPS™

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: June 1, 2017

Device Name: EXCELSIUS GPS™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Predicates: EXCELSIUS GPS™
Primary predicate: StealthStation (K133444)
Additional predicate: ROSA Spine (K151511)

EXCELSIUS GPS™ Instruments
Additional predicates:
CREO® (K143633)
REVERE® (K133350)
REVOLVE® (K111449)
QUARTEX™ (K161591)
ELLIPSE® (K123783)
SI-LOK® (K112028)
CAPTIVATE™ (K162825)

Purpose:

The purpose of this submission is to request clearance of EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments.

Device Description:

The EXCELSIUS GPS™ is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera. The navigation and guidance system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's

anatomy). Once this registration is created, the software displays the relative position of a tracked instrument, including the end effector of the robotic arm, on the patient images. This visualization can help guide the surgeon's planning and approach. As an aid to visualization, the surgeon can plan implant placement on the patient images prior to surgery. The information of the plan coupled with the registration provides the necessary information to provide visual assistance to the surgeon during free hand navigation or during automatic robotic alignment of the end effector. During surgery, the system tracks the position of GPS compatible instruments, including the end effector of the robotic arm, in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. Standard non-navigated metallic instruments that fit through the guide tube at the selected trajectory may be used without navigation while the guide tube is stationary, for uses such as bone preparation (e.g. rongeurs, reamers etc.) or placing implants (e.g. rod inserters, locking cap drivers) that are not related to screw placement. Navigation can also be performed without guidance. System software is responsible for all motion control functions, navigation functions, data storage, network connectivity, user management, case management, and safety functions. EXCELSIUS GPS™ surgical instruments are non-sterile, re-usable instruments that can be operated manually or with the use of the positioning system.

EXCELSIUS GPS™ instruments consist of registration instruments, patient reference instruments, surgical instruments, and end effectors. Registration instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification probe, surveillance marker, surgical instrument arrays, intra-op CT registration fixture, fluoroscopy registration fixture, and dynamic reference base (DRB). Patient reference instruments are either clamped or driven into any appropriate rigid anatomy that is considered safe and provides a point of rigid fixation for the DRB. Surgical instruments are used to prepare the implant site or implant the device, and include awls, drills, drivers, taps, and probes. End effectors are wirelessly powered guide tubes that attach to the distal end of the robotic arm and provide a rigid structure for insertion of surgical instruments.

Indications for Use:

The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

Technological Characteristics:

The EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments have similar technological characteristics to the predicate devices including the main system

components, workflow, user interface, software features, and design. The EXCELSIUS GPS™ System is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation. The table below provides a comparison of technological characteristics and principles of operation for the subject EXCELSIUS GPS™ and the predicate devices.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Principle of operation	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments - Guidance of instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative images - Patient registration - Surgical planning - Guidance of instruments
Input images	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D intra-operative exam
Integrated planning software	EXCELSIUS™ GPS Planning and Navigation Application software	Synergy Spine software	Rosanna Spine (Medtech)
Save/load planning	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes
Trajectory planning parameters	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter
Localization means	Optical system (infrared camera)	Optical (infrared camera) or electromagnetic system	Robot arm absolute encoders and optical system (infrared camera)
Image-guided	Yes	Yes	Yes
Controller	Force-controlled movement allowing robotic arm positioning	No controller; instruments are manually positioned by the surgeon.	Axis controller per joint Kinematic transformation Supervisor module
Patient registration method	Intra-op CT: Registration fixture Pre-op CT: Fluoroscopic to pre-op CT merge Fluoroscopy: Registration fixture	Point-to-point registration with anatomical markers Intra-op CT: Calibrated CT gantry to camera merge Pre-op CT: Point merge Fluoroscopy: Registration fixture	3D registration with X-Ray pattern containing radiopaque markers
Accuracy verification on anatomical landmarks	Yes (probe)	Yes (probe)	Yes (probe)
Real time display of instrument position	Yes	Yes	Yes

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Provide guide for instruments	Yes, instruments are used through the guide tube on the robotic arm or are manually positioned by the surgeon.	No, instruments are manually positioned by the surgeon.	Yes, instruments are mounted onto the robotic arm.
Patient fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is fixed to the patient's iliac crest or clamped on the spinous for tracking system	Reference is fixed to the patient's iliac crest for tracking system

Performance Testing:

Verification and validation testing was conducted on EXCELSIUS GPS™ to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation
- Surgical simulations conducted on phantom models
- Human cadaveric quantitative validation under clinically relevant scenarios
- Compliance conformity assessments per:
 - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
 - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance - Usability

Biocompatibility:

The biocompatibility evaluation for EXCELSIUS GPS™ has been conducted in accordance with ISO 10993 standards and blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", May 1, 1995 and FDA Guidance "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," June 16, 2016. The evaluation confirms that EXCELSIUS GPS meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:

Testing was performed to assure compliance with recognized safety standards: IEC 60601-1:2012 standard for electrical safety and IEC 60601-1-2:2014 standard for electromagnetic compatibility.

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained

in Medical Devices (May 11, 2005) and IEC 62304:2006-05 Medical Device Software – Software life cycle processes. The software for this device is considered a “MAJOR” level of concern.

Basis of Substantial Equivalence:

EXCELSIUS GPS™ has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.



FDA U.S. FOOD & DRUG
ADMINISTRATION

July 10, 2020

Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K200047

Trade/Device Name: ExcelsiusGPS Cranial 1.0 Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: June 11, 2020
Received: June 12, 2020

Dear Jennifer Antonacci:

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 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

K200047 - Jennifer Antonacci

Page 2

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,

Adam D. Pierce -S
2020.07.10 17:31:58 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K200047

Device Name

ExcelsiusGPS Cranial 1.0 Module

Indications for Use (Describe)

The ExcelsiusGPS is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

510(k) Summary: ExcelsiusGPS Cranial 1.0 Module

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: July 10, 2020

Device Name: ExcelsiusGPS® Cranial 1.0 Module

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO, HAW
Regulatory Class: II

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Medtronic StealthStation S8 (K162309)
ROSA ONE Brain (K182417)

Purpose:

The purpose of this submission is to request clearance of the ExcelsiusGPS® Cranial 1.0 Module software and navigated instruments for access, preparation, and placement of cranial devices.

Device Description:

The ExcelsiusGPS® Cranial Module includes hardware and software that enables real time surgical navigation using radiological patient images (MRI, CT, and fluoroscopy), using a dynamic reference base and positioning camera. The navigation system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument on the patient images. As an aid to visualization, the surgeon can plan trajectories for instrument placement on the patient images prior to surgery. Registration provides the necessary information to provide visual assistance to the surgeon during freehand navigation. During surgery, the system tracks the position of GPS compatible instruments in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. System software is responsible for all

navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusGPS® surgical instruments include non-sterile, re-usable instruments and sterile instruments that are operated manually or with the use of the positioning system.

The ExcelsiusGPS® Cranial Module is designed to assist with stereotactic procedures that include guidance to cranial targets for instrument navigation and device placement. Instruments consist of end effector instruments, registration instruments, navigated instruments, patient positioning instruments, and surgical instruments. End effector instruments include instruments to connect to the Interchangeable Guide End Effector. Registration and navigated instruments incorporate unique array patterns with reflective markers, and are used to track patient anatomy and surgical instruments. Patient positioning instruments aid in patient fixation. Surgical instruments are used to access and prepare the local site and place devices, such as needles, electrodes, and tubes. The ExcelsiusGPS® Cranial Module is suitable for use in adult and pediatric patient populations in which the use of stereotactic neurosurgery may be appropriate.

Indications for Use:

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

Technological Characteristics:

The ExcelsiusGPS® Cranial Module and associated instruments have similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. The ExcelsiusGPS® Cranial Module is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
Principle of operation	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/preoperative images - Patient registration - Surgical planning	- Intraoperative/preoperative images - Patient registration - Surgical planning - Guidance of instruments

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
	- Guidance of instruments	- Guidance of instruments	- Real-time tracking of navigated instruments	
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software	Stealthstation Cranial	ROSANNA BRAIN
Save/load planning	Yes	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes	Yes
Image-guided	Yes	Yes	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Fluoroscopy: Registration Fixture Stereotactic Localizer Registration	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture	Point-to-point registration with anatomical markers or skin/bone fiducials Optical or electromagnetic trace merge Intra-Op CT: Calibrated CT gantry to camera merge Stereotactic Localizer Registration	Point-to-point registration with anatomical markers or skin/bone fiducials Stereotactic Localizer Registration Optical surface registration
Accuracy verification on anatomical landmarks	Yes	Yes	Yes	Yes
Real time display of instrument position	Yes	Yes	Yes	Yes
Patient fixation	Reference is attached to patient head holder Head is fixed to patient stabilization stand	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is attached to patient head holder	Head is fixed onto robot arm's flange

Performance Testing:

Verification and validation testing was conducted on ExcelsiusGPS® Cranial Module to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Surgical simulations conducted on phantom models - cranial sawbone models and registration matrix were used to quantify accuracy in a controlled setting
- Human cadaveric quantitative validation under clinically relevant scenarios - demonstrated system accuracy in navigating cranial devices to the desired location on patient images
- Compliance conformity assessments per:
 - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability
- Navigational accuracy of the subject device system with mean, standard deviation, and 99% confidence interval (CI). Results demonstrate the subject device meets the accuracy acceptance criteria for position and angle as follows:

Position		Angle	
Mean	99% CI	Mean	99% CI
< 1.5mm	≤ 2mm	< 2.0°	≤ 2°

Biocompatibility:

The biocompatibility evaluation for ExcelsiusGPS® has been conducted in accordance with FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process'," June 16, 2016. The evaluation confirms that ExcelsiusGPS® meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:

Testing was performed to assure compliance with recognized safety standard: IEC 60601-1:2012 standard for electrical safety. Electromagnetic compatibility was not affected.

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.

Basis of Substantial Equivalence:

ExcelsiusGPS® Cranial Module has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.



August 25, 2021

Globus Medical Inc.
Kelly Baker
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K211616
Trade/Device Name: ExcelsiusHub
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 25, 2021
Received: May 26, 2021

Dear Kelly Baker:

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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

K211616 - Kelly Baker

Page 2

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,

Jesse Muir -S

For: Shumaya Ali, M.P.H.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K211616

Device Name

ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion 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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

510(k) Summary: ExcelsiusHub™ System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: August 23, 2021

Device Name: ExcelsiusHub™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Excelsius3D™ Imaging System (K210912)

Purpose:

The purpose of this submission is to request clearance for the ExcelsiusHub™.

Device Description:

The ExcelsiusHub™ is a navigation system that includes hardware and software that enables real time surgical visualization using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), a dynamic reference base, and a camera tracking system. The navigation system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument on the patient images. This visualization can help guide the surgeon's planning and approach for implant placement. The patient's scan coupled with the registration provides visual assistance to the surgeon when using the system for free hand navigation. During surgery, the system tracks the position of compatible instruments in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. System software is responsible for all navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusHub™ uses the same instruments as ExcelsiusGPS®.

ExcelsiusHub™ may be used in conjunction with ExcelsiusGPS® for guidance of navigated instruments along a planned trajectory using a robotic arm. When connected to ExcelsiusGPS®, ExcelsiusHub™ software is responsible for both navigation and guidance.

Indications for Use:

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Technological Characteristics:

The ExcelsiusHub™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. ExcelsiusHub™ is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Principle of operation	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments - Guidance of instruments
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software
Save/load planning	Yes	Yes
Merge images functionality	Yes	Yes
Image-guided	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture

Device	Subject ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Accuracy verification	Yes	Yes
Real time display of instrument position	Yes	Yes
Patient fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system

*Excelsius3D 510(k) under FDA review (remove *s and this note upon clearance)

Performance Testing:

Verification and validation testing were conducted on ExcelsiusHub™ to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Surgical simulations conducted on phantom models
- Qualitative validation to confirm intended use
- Electrical Safety and Electromagnetic Compatibility
 - Testing was performed to assure compliance with recognized safety standards for electrical safety and electromagnetic compatibility
 - IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
 - IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: *Electromagnetic disturbances*
 - IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: *Usability*
 - IEC 62304:2015 Medical device software - Software lifecycle processes
 - IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices

Software Verification and Validation Testing:

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.

Basis of Substantial Equivalence:

ExcelsiusHub™ has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use.

The information provided within this premarket notification supports substantial equivalence to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

January 30, 2015

Globus Medical, Incorporated
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K143633

Trade/Device Name: CREO® Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: January 5, 2015
Received: January 6, 2015

Dear Dr. Baker:

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. 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 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); good manufacturing practice requirements as set

Page 2 – Kelly J. Baker, Ph.D.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K143633

Device Name

CREO® Stabilization System

Indications for Use (Describe)

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO® 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO® Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

"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."

510(k) Summary: CREO® Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: January 30, 2015

Device Name: CREO® Stabilization System

Classification: Per 21 CFR as follows:
§888.3070* Spondylolisthesis Spinal Fixation Device System
System
§888.3070 Pedicle Screw Spinal System, Adolescent
Idiopathic Scoliosis
§888.3070 Pedicle Screw Spinal System
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Codes NKB*, OSH, MNH, MNI, KWQ, KWP
Regulatory Class III* and II, Panel Code 87.
**Primary*

Primary Predicate: CREO® Stabilization System (K124058)

Purpose:

The purpose of this submission is to request clearance for additional cobalt chrome implants for the CREO® Stabilization System.

Device Description:

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO® implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO® Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

CREO® implants are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

Indications for Use:

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO® 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion

(pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/iliac.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO® Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Technological Characteristics:

The technological characteristics of the CREO® Stabilization System additional implants are similar to the predicate device in terms of design, dimensions, intended use, materials, and performance characteristics.

Performance Data:

Engineering analysis and mechanical testing (static and dynamic compression and static torsion) conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004, were provided in support of substantial equivalence.

Basis of Substantial Equivalence:

CREO® additional implants are similar to the predicate device with respect to technical characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device. CREO® additional implants perform as well as or better than the predicate device.

510(k) Summary: CREO™ Stabilization System

MAY 13 2013

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: May 3, 2013

Device Name: CREO™ Stabilization System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
§888.3070 Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
Product Codes MNH, MNI, KWQ, KWP, NKB, OSH
Regulatory Class II and III, Panel Code 87.

Predicate(s): REVERE® Stabilization System K122226
REVERE® 4.5 Stabilization System K113395
Medtronic CD Horizon® Spinal System K102807
Synthes USS (including Matrix and Click'X) Spinal System.
K031175, K100952 & K103287
DePuy VIPER® 2 System K111136

Purpose:

The purpose of this submission is to request clearance of the CREO™ Stabilization System.

Device Description:

The CREO™ Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO™ implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO™ Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. All other CREO™ implants are composed of titanium alloy or stainless steel, as specified in ASTM F136, F1295, F67 and F138. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

Indications for Use:

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO™ 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/iliac.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO™ Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO™ Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Performance Data:

Mechanical testing (static and dynamic compression, and static torsion) was conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Conclusions / Basis of Substantial Equivalence:

The CREO™ Stabilization System implants are similar to the predicate implants with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. CREO™ implants are as safe, as effective, and perform as well as or better than the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Incorporated
% Ms. Sarah M. Fitzgerald
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Letter dated: May 13, 2013

Re: K124058
Trade/Device Name: CREO™ Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: April 19, 2013
Received: April 22, 2013

Dear Ms. Fitzgerald:

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. 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 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); good manufacturing practice requirements as set

Page 2 – Ms. Sarah M. Fitzgerald

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement510(k) Number: K124058Device Name: CREO™ Stabilization System**INDICATIONS:**

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO™ 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO™ Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO™ Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K124058

Attachment D: Recognized Consensus Standards

The QUARTEX devices described in this premarket notification conform with the requirements of the FDA recognized consensus standards listed in **Table 1**.

Table 1: FDA Recognized Standards

FDA Recognition Number	Standard Number	Standard Organization	Standard Title
(b)(4)			
14-501	F1886/F1886M-16	ASTM	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection
11-388	F1717-21	ASTM	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
14-511	ST79:2017	AAMI / ANSI	Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
14-409	11137-2:2013	AAMI / ANSI / ISO	Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
14-530	11607-1 Second Edition 2019-02	ISO	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging
14-333	17665-1:2006/(R)2013	ANSI / AAMI / ISO	Sterilization Of Health Care Products -- Moist Heat -- Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices
2-258	10993-1 Fifth Edition 2018-08	ISO	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

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Mechanical Testing Reports

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- Design Verification Procedure, QUARTEX Instrumentation Integration

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Approvals

Legend: Y = Required, N = Not required, ? = As needed

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Page 1 of 59

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QUARTEX MIS Quantitative Validation Summary

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Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: March 11, 2024

Reviewer: Michael Molyneaux-Francis

510(k)# K231850/S001 **Subject:** Traditional

Applicant: Globus Medical Inc

Contact Name: Jennifer Antonacci

Correspondent Firm: Globus Medical Inc

Received Date: February 12, 2024

Pro Code(s): NKG **Class:** II **Reg #:** 888.3075

Pro Code(s): KWP **Class:** II **Reg #:** 888.3050

Pro Code(s): OLO **Class:** II **Reg #:** 882.4560

Device Trade Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Title: Group Manager, Regulatory Affairs

Phone: (610) 930-1800 **(b)(6)** **Email:** **(b)(6)**

Due Date: March 14, 2024

Reg Name: Posterior Cervical Screw System

Reg Name: Spinal Interlaminar Fixation Orthosis

Reg Name: Stereotaxic Instrument

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161591	NKG, KWP, OLO	QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K211957	NKG, KWP, OLO	QUARTEX Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K200047	OLO, HAW	ExcelsiusGPS Cranial 1.0 Module	Globus Medical Inc.
K211616	OLO	ExcelsiusHub	Globus Medical Inc.

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Reviewer Sign-Off	Michael S. Molyneaux-francis -S Digitally signed by Michael S. Molyneaux-francis -S Date: 2024.03.13 19:08:52 -04'00'



U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: August 21, 2023

Reviewer: Michael Molyneaux-Francis

510(k)# K231850 **Subject:** Traditional

Applicant: Globus Medical Inc

Contact Name: Jennifer Antonacci

Correspondent Firm: Globus Medical Inc

Received Date: June 23, 2023

Pro Code(s): NKG **Class:** II **Reg #:** 888.3075

Pro Code(s): KWP **Class:** II **Reg #:** 888.3050

Pro Code(s): OLO **Class:** II **Reg #:** 882.4560

Device Trade Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Title: Group Manager, Regulatory Affairs

Phone: (610) 930-1800 **(b)(6)** **Email:**
(b)(6)

Due Date: September 21, 2023

Reg Name: Posterior Cervical Screw System

Reg Name: Spinal Interlaminar Fixation Orthosis

Reg Name: Stereotaxic Instrument

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161591	NKG, KWP, OLO	QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K211957	NKG, KWP, OLO	QUARTEX Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments	Globus Medical Inc.
K200047	OLO, HAW	ExcelsiusGPS Cranial 1.0 Module	Globus Medical Inc.
K211616	OLO	ExcelsiusHub	Globus Medical Inc.

Recommendation

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U.S. FOOD & DRUG
ADMINISTRATION

March 14, 2024

Globus Medical Inc
Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K231850

Trade/Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS®
Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, KWP, OLO

Dated: February 9, 2024

Received: February 12, 2024

Dear Jennifer Antonacci:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin
O'Neill -S 

Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 6/23/2023 3:07:03 PM
To: (b)(6)
CC: DCCLetters@fda.hhs.gov
Subject: K231850 Acknowledgement Letter
Attachments: K231850-Acknowledgement Letter.pdf

June 23, 2023

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.

The CDRH Portal is now available:

Instead of shipping your submissions to us, you can now upload them at our [CDRH Portal](#).

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



**U.S. FOOD & DRUG
ADMINISTRATION**

Acknowledgement Letter

06/23/2023

Jennifer Antonacci Ph.D., Group Manager, Regulatory Affairs
Globus Medical Inc
2560 General Armistead Ave
Audubon, PA 19403
UNITED STATES

Dear Jennifer Antonacci Ph.D.:

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: K231850

Received: 06/23/2023

Applicant: Globus Medical Inc

Device: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

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

Good morning, Jennifer,

Thank you for your timely responses and your most recent query. In addition, I apologize if I have caused any confusion on your end. Based on your most recent response (K231850 Interactive Response follow up 15Aug2023.pdf), I see that the (b)(4) (b)(4) (b)(4) (b)(4) Per my review of this submission (K231850), I will proceed with the information presented in your two (2) Device Specific Inserts.

Respectfully,

Michael

Michael S. Molyneaux-Francis

General Engineer / Lead Reviewer

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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

Office Ph: (240) 402-5178

Michael.Molyneaux-Francis@fda.hhs.gov<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>

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From: Jennifer Antonacci (b)(6)

Sent: Tuesday, August 15, 2023 6:00 PM

To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Subject: [EXTERNAL] RE: K231850 - Interactive Requests

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Hi Michael,

(b)(4)

Please see attached for further clarification and detailed responses to your additional questions.

Thank you,

Jennifer

[cid:image007.png@01D9CFA6.1D521660]<http://secure-web.cisco.com/16uR_1o_ThAiWSQXLXsTRho2QliHKfgW9ct6SkrqdSfamiD9y4V27CJtuPFTGHQshUwQkWFhsq6e9KmgF-jNjg_8IV42o802bGknPZLg8Ahzu-KGX-GIpjuIfv0KjoLfYzSxCzquOsZ6UmN-GydLT3Ew21Kd8z8IZx3RwE5VUzuK39-ylkKx5QUS0DrE86aGoPh6Y1MDt65oODXR9ql676buqiM44bPXglEZTSknNpsGM/http%3A%2F%2Fwww.globusmedical.com%2F>

Jennifer Antonacci

, Ph.D.

|

Group Manager, Regulatory Affairs

Globus Medical, Inc.

Valley Forge Business Center

2560 General Armistead Avenue | Audubon, PA 19403

Ph: (610) 930-1800

ext.

(b)(6)

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Fax: 610-930-2042<fax:610-930-2042>

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[cid:image009.png@01D9CFA6.1D521660]<https://www.google.com/maps/place/2560+General+Armistead+Ave,+Eagleville,+PA+19403/@40.1200296,-75.4002192,17z/data=!3m1!4b1!4m5!3m4!1s0x89c696854623b3bb:0xbe9c99708978a5e6!8m2!3d40.1200255!4d-75.3980305>

[cid:image010.png@01D9CFA6.1D521660]<mailto:jantonacci@globusmedical.com>

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>>

Sent: Tuesday, August 15, 2023 3:16 PM

(b)(6)

Subject: [External Sender] RE: K231850 - Interactive Requests

Importance: High

Hello Jennifer,

Thank you for the quick responses to the interactive requests!

(b)(4)

(b)(4)

(b)(4) Please provide your response to the follow-up interactive requests listed below, by noon EST, Thursday, August 17th, 2023. The follow-up interactive requests are as follows:

FOLLOW-UP INTERACTIVE REQUESTS

(b)(4)

Please refer to the forwarded email below for more information regarding these follow-up interactive requests. Also, please reach out if you have any questions, comments or concerns.

Respectfully,

Michael

Michael S. Molyneaux-Francis

General Engineer / Lead Reviewer

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

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[cid:image003.jpg@01D9CFA6.1D521660] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D9CFA6.1D521660] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image005.jpg@01D9CFA6.1D521660] <https://protect-us.mimecast.com/s/3-VZCQWKWMilGzLPUAgNnu/> [cid:image006.jpg@01D9CFA6.1D521660]

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From: Jennifer Antonacci

(b)(6)

Sent: Tuesday, August 15, 2023 1:46 PM

To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov<mailto:Michael.Molyneaux-Francis@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K231850 - Interactive Requests

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Hi Michael,

Please see attached for our responses to your interactive questions sent on August 14th.

Please let me know if you have any further questions.

Kind regards,

Jennifer

[cid:image007.png@01D9CFA6.1D521660]<http://secure-web.cisco.com/1YqzyMNqC4bn4bGRbF4pQ5dsiaTbbU1cfGuzMqtcbsT8BOV08UrvJpetb1Pl-JxMKLY4rPSRu4BzxIOc9Y9lRl2ptSHUvW9VESpMhnuUYMcgTlUbeRamL0vVuebd30swPOddhqAYBQP7YmZXokTe c15XIAISiYLRkyh2pqOVjWzD-M5qqfz16DXSDWOF1XnMCYulk-pWUT1sFXjXgRB-Q1Q/http%3A%2F%2Fwww.globusmedical.com%2F>

Jennifer Antonacci

, Ph.D.

|

Group Manager, Regulatory Affairs

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[cid:image010.png@01D9CFA6.1D521660]<<mailto:jantonacci@globusmedical.com>>

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Sent: Monday, August 14, 2023 5:01 PM

To: Jennifer Antonacci

(b)(6)

Subject: [External Sender] K231850 - Interactive Requests

Hello Dr. Jennifer Antonacci,

I am the Lead Reviewer for K231850, in which you are seeking clearance of additional QUARTEX[®] implants and instruments, as well as ExcelsiusGPS[®] instruments for use with the ExcelsiusGPS[®] and ExcelsiusHub[®],[®] navigation systems. I have come across a couple of issues in the file that I believe can be interactively addressed in a short amount of time. Please respond to the interactive requests (below) by 4pm, Tuesday, August 15th, 2023. Please inform if you will be unable to do so by that date and time. (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Please reach out if you have any questions, comments and/or concerns regarding these interactive requests.

Respectfully,

Michael

Michael S. Molyneaux-Francis

General Engineer / Lead Reviewer

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

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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 views expressed.

Good morning, Jennifer,

Thank you for your timely responses and your most recent query. In addition, I apologize if I have caused any confusion on your end. Based on your most recent response (K231850 Interactive Response follow up 15Aug2023.pdf), I see that (b)(4)

Respectfully,

Michael

Michael S. Molyneaux-Francis

General Engineer / Lead Reviewer

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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

Office Ph: (240) 402-5478

Michael.Molyneaux-Francis@fda.hhs.gov



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From: Jennifer Antonacci (b)(6)
Sent: Tuesday, August 15, 2023 6:00 PM
To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231850 - Interactive Requests

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Hi Michael,

(b)(4)

Please see attached for further clarification and detailed responses to your additional questions.

Thank you,
Jennifer

Jennifer Antonacci, Ph.D. | Group Manager, Regulatory Affairs

Globus Medical, Inc.

Valley Forge Business Center

2560 General Armstrong Avenue, Audubon, PA 19403

Ph: (610) 930-1800 (b)(6) Fax: 610-930-2042

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Sent: Tuesday, August 15, 2023 3:16 PM
To: Jennifer Antonacci (b)(6)
Subject: [External Sender] RE: K231850 - Interactive Requests
Importance: High

Hello Jennifer,

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(b)(4) Please provide your response to the follow-up interactive requests listed below, by noon EST, Thursday, August 17th, 2023. The follow-up interactive requests are as follows:

FOLLOW-UP INTERACTIVE REQUESTS

(b)(4)

(b)(4)

Please refer to the forwarded email below for more information regarding these follow-up interactive requests. Also, please reach out if you have any questions, comments or concerns.

Respectfully,

Michael

Michael S. Molyneaux-Francis
General Engineer / Lead Reviewer

CHT6B: Division of Spinal Devices
CHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

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Kind regards,
Jennifer

Jennifer Antonacci, Ph.D. | Group Manager, Regulatory Affairs



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Sent: Monday, August 14, 2023 5:01 PM
To: Jennifer Antonacci (b)(6)
Subject: [External Sender] K231850 - Interactive Requests

Hello Dr. Jennifer Antonacci,

I am the Lead Reviewer for K231850, in which you are seeking clearance of additional QUARTEX® implants and instruments, as well as ExcelsiusGPS® instruments for use with the ExcelsiusGPS® and ExcelsiusHub™ navigation systems. I have come across a couple of issues in the file that I believe can be interactively addressed in a short amount of time. Please respond to the interactive requests (below) by **4pm, Tuesday, August 15th, 2023**. Please inform if you will be unable to do so by that date and time. The two (2) interactive requests are as follows:

(b)(4)

(b)(4)

 Table

Description automatically generated

(b)(4)

Please reach out if you have any questions, comments and/or concerns regarding these interactive requests.

Respectfully,
Michael

Michael S. Molyneaux-Francis
General Engineer / Lead Reviewer

DHT6S: Division of Spinal Devices
OHT6: Office of Orthopedic Devices

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

Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

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Office Ph: (240) 402-5178
Michael.Molyneaux-Francis@fda.hhs.gov



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July 5, 2023</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your submission K231850, 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.</p>

<p>The lead reviewer assigned to your submission is me, Michael Molyneaux-Francis. The file is being reviewed in Office of Health Technology 6, Division of Health Technology 6 B. The first line supervisor is the Assistant Director, Extracolumnar Spinal 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.</p>

<p>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. </p>

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

<p>*** This is a system-generated email notification ***</p>

510(k) Summary: QUARTEX® Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: March 13, 2024

Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System
ExcelsiusGPS® Instruments

Classification: QUARTEX® OCT Spinal System
Per 21 CFR §888.3075 Posterior Cervical Screw System
Product Code : NKG
Regulatory Class: II, Panel Code: 87

Per 21 CFR §888.3050 Spinal Interlaminar Fixation Orthosis
Product Code : KWP
Regulatory Class: II, Panel Code: 87

ExcelsiusGPS® & ExcelsiusHub™
Per 21 CFR §882.4560 Stereotaxic Instruments
Product Code: OLO
Regulatory Class: II, Panel Code: 87

Primary Predicate: QUARTEX® Spinal System (K161591)
Addtl Predicates: QUARTEX® Spinal System (K211957)
ExcelsiusGPS® (K171651, K200047)
ExcelsiusHub™ (K211616)
Reference Device: CREO® Stabilization System (K143633, K124058, K191835)

Purpose:
The purpose of this submission is to request clearance for additional QUARTEX® implants and instruments, and additional ExcelsiusGPS® instruments.

Device Description:

QUARTEX® additional implants include monoaxial, polyaxial, and dual lead polyaxial screws manufactured from titanium alloy; MIS rods manufactured from titanium alloy, stainless steel, and/or cobalt chromium molybdenum; and, associated manual and navigated surgical instruments.

ExcelsiusGPS® Instruments are nonsterile, reusable instruments that can be used with ExcelsiusGPS® or ExcelsiusHub® and may be used for a navigated surgical procedure. No changes were made to the ExcelsiusGPS® or ExcelsiusHub® systems with the addition of the subject ExcelsiusGPS® instruments.

Indications for Use:

QUARTEX® OCT Spinal System

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

ExcelsiusGPS®

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

ExcelsiusHub™

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Performance Data:

Mechanical testing (static and dynamic compression bending) was conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004, to demonstrate substantial equivalence to the predicate devices. Verification and validation testing were conducted to confirm implant placement accuracy with ExcelsiusGPS®.

Technological Characteristics:

Subject implants and instruments have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

Subject QUARTEX[®] implants and instruments and ExcelsiusGPS[®] instruments have are similar to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 2/12/2024 3:31:29 PM
To: (b)(6)
CC: DCCLetters@fda.hhs.gov
Subject: K231850/S001 Acknowledgement Letter
Attachments: K231850-S001-Acknowledgement Letter.pdf

February 12, 2024

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.

The CDRH Portal is now available:

Instead of shipping your submissions to us, you can now upload them at our [CDRH Portal](#).

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Acknowledgement Letter

02/12/2024

Jennifer Antonacci Ph.D., Group Manager, Regulatory Affairs
Globus Medical Inc
2560 General Armistead Ave
Audubon, PA 19403
UNITED STATES

Dear Jennifer Antonacci Ph.D.:

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. Failure to do so may result in processing delays. Please send any future correspondence through the CDRH Portal. For more information on the CDRH Portal, please visit [CDRH Portal](#). 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: K231850/S001

Received: 02/12/2024

Applicant: Globus Medical Inc

Device: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

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



U.S. FOOD & DRUG
ADMINISTRATION

March 14, 2024

Globus Medical Inc
Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K231850

Trade/Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS®
Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, KWP, OLO

Dated: February 9, 2024

Received: February 12, 2024

Dear Jennifer Antonacci:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin
O'Neill -S 

Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

K231850

Device Name

QUARTEX® Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.**Indications for Use**510(k) Number (if known)
K231850Device Name
ExcelsiusGPS®

Indications for Use (Describe)

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

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

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K231850

Device Name

ExcelsiusHub™

Indications for Use (Describe)

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion 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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PRAStaff@fda.hhs.gov

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510(k) Summary: QUARTEX® Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: March 13, 2024

Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System
ExcelsiusGPS® Instruments

Classification: QUARTEX® OCT Spinal System
Per 21 CFR §888.3075 Posterior Cervical Screw System
Product Code : NKG
Regulatory Class: II, Panel Code: 87

Per 21 CFR §888.3050 Spinal Interlaminar Fixation Orthosis
Product Code : KWP
Regulatory Class: II, Panel Code: 87

ExcelsiusGPS® & ExcelsiusHub™
Per 21 CFR §882.4560 Stereotaxic Instruments
Product Code: OLO
Regulatory Class: II, Panel Code: 87

Primary Predicate: QUARTEX® Spinal System (K161591)
Addtl Predicates: QUARTEX® Spinal System (K211957)
ExcelsiusGPS® (K171651, K200047)
ExcelsiusHub™ (K211616)
Reference Device: CREO® Stabilization System (K143633, K124058, K191835)

Purpose:
The purpose of this submission is to request clearance for additional QUARTEX® implants and instruments, and additional ExcelsiusGPS® instruments.

Device Description:

QUARTEX® additional implants include monoaxial, polyaxial, and dual lead polyaxial screws manufactured from titanium alloy; MIS rods manufactured from titanium alloy, stainless steel, and/or cobalt chromium molybdenum; and, associated manual and navigated surgical instruments.

ExcelsiusGPS® Instruments are nonsterile, reusable instruments that can be used with ExcelsiusGPS® or ExcelsiusHub® and may be used for a navigated surgical procedure. No changes were made to the ExcelsiusGPS® or ExcelsiusHub® systems with the addition of the subject ExcelsiusGPS® instruments.

Indications for Use:

QUARTEX® OCT Spinal System

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

ExcelsiusGPS®

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

ExcelsiusHub™

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Performance Data:

Mechanical testing (static and dynamic compression bending) was conducted in accordance with ASTM F1717 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004, to demonstrate substantial equivalence to the predicate devices. Verification and validation testing were conducted to confirm implant placement accuracy with ExcelsiusGPS®.

Technological Characteristics:

Subject implants and instruments have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

Subject QUARTEX[®] implants and instruments and ExcelsiusGPS[®] instruments have are similar to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.



Valley Forge Business Center
2560 General Armistead Avenue Audubon, PA 19403
Phone: 610.930.1800 Fax: 610.930.2042
Order Fax: 610.930.2041
www.globusmedical.com

February 9, 2024

FDA/CDRH/DCC

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
Attn: Michael Molyneaux-Francis

FEB 12 2024

RECEIVED

K231850/S001

Re: K231850/S1 QUARTEX Additional Implants

Dear Mr. Molyneaux-Francis,

This submission is in response to the deficiency letter dated August 21, 2023 requesting additional information. The original questions are identified in bold font, and the responses are identified in standard font. An eCopy is enclosed.

Globus believes that the information provided in this response is sufficient to address the deficiencies. Please feel free to contact me at (610) 930-1800 (b)(6) or by email at (b)(6)

Sincerely,

(b)(6)

Senior Group Manager, Regulatory Affairs
Globus Medical, Inc.

Enclosed:
K231850/S1 eCopy

August 21, 2023</br></br><p>We have reviewed your submission. Please see attached.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Michael Molyneaux-Francis. </p>

<p>*** This is a system-generated email notification ***</p>



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

Convert to PDF

K231850

Globus Medical Inc

Trade/Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Name: Dr. Jennifer Antonacci

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K231850 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K231850 to:

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

Please refer to the eCopy guidance at <https://www.fda.gov/media/83522/download> for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (<https://www.fda.gov/media/71735/download>) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

(b)(4)

MINOR DEFICIENCY LIST

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at <https://www.fda.gov/media/114034/download>.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.



U.S. FOOD & DRUG
ADMINISTRATION

K231850

Globus Medical Inc

Trade/Device Name: QUARTEX® Occipito-Cervico-Thoracic Spinal System ExcelsiusGPS® Instruments

Contact Name: Dr. Jennifer Antonacci

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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

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(b)(4)

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Expert Response to Questions

Date: March 14, 2024

Expert Reviewer: Michel D Janda

Expertise: Stereotaxic

Applicable Review Guide (if used): Not Applicable

Submission # K231850/S001

Applicant: Globus Medical Inc

Device Trade Name: QUARTEX®
Occipito-Cervico-Thoracic Spinal
System ExcelsiusGPS® Instruments

Optional Classification Information:

Pro Code(s): NKG, KWP, OLO **Class:** II **Reg #:**
888.3075

Reg Name: Posterior Cervical
Screw System

Rx/OTC: Rx

I. Expert Review Summary

(b)(5)

(b)(5)

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(b)(5)

Digital Signature Table (Doc#: 04504.02.03)		
Expert Sign-Off	Michel D. Janda -S	Digitally signed by Michel D. Janda -S Date: 2024.03.14 09:24:32 -04'00'

From: Janda, Michel D
To: Molyneaux-Francis, Michael
Subject: (b)(5)
Date: Tuesday, March 5, 2024 10:28:21 AM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
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[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)

Michael,

(b)(5)

Thank you,

Michel



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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Sent: Monday, March 4, 2024 3:38 PM

To: Janda, Michel D <Michel.Janda@fda.hhs.gov>

Subject: RE: (b)(5)

Hello Michel.

(b)(5)

Thank you,
Michael

Michael S. Molyneaux-Francis, FE

General Engineer / Lead Reviewer, OHT6B: Division of Spinal Devices



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ADMINISTRATION**

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From: Janda, Michel D <Michel.Janda@fda.hhs.gov>

Sent: Monday, March 4, 2024 9:23 AM

To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Subject: RE: (b)(5)

Hi Michael,

(b)(5)

(b)(5)

Michel

From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>

Sent: Monday, March 4, 2024 6:49 AM

To: Janda, Michel D <Michel.Janda@fda.hhs.gov>

Subject: RE: (b)(5)

Good morning Michel,

(b)(5)

Thank you,
Michael

Michael S. Molyneaux-Francis, FE

General Engineer / Lead Reviewer, OHT6B: Division of Spinal Devices



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ADMINISTRATION**

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From: Molyneaux-Francis, Michael

Sent: Wednesday, February 14, 2024 4:23 PM

To: Janda, Michel D <Michel.Janda@fda.hhs.gov>

Subject: RE: (b)(5)

Michel,

Thank you for agreeing to the consult

(b)(5)

(b)(5)

-Michael

Michael S. Molyneaux-Francis, FE
General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-5178
Michael.Molyneaux-Francis@fda.hhs.gov



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ADMINISTRATION



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From: Janda, Michel D <Michel.Janda@fda.hhs.gov>
Sent: Wednesday, February 14, 2024 4:12 PM
To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Subject: RE: (b)(5)

Yes, I can consult on this file.

Michel

From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Sent: Wednesday, February 14, 2024 9:21 AM
To: Janda, Michel D <Michel.Janda@fda.hhs.gov>
Subject: RE: (b)(5)

Hello Michel,

(b)(5)

Regards,
Michael
Michael S. Molyneaux-Francis
General Engineer / Lead Reviewer

Extracolumnar Spinal Devices Team
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-5178
Michael.Molyneaux-Francis@fda.hhs.gov



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From: Janda, Michel D <Michel.Janda@fda.hhs.gov>
Sent: Friday, August 18, 2023 5:48 PM
To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Subject: (b)(5)

Hi Michael,

(b)(5)

Sincerely,

CDR Michel Janda, MS, USPHS
Lead Reviewer

Stereotaxic, Bone Growth Stimulators, 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 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Office: (301) 796-6395 Email: michel.janda@fda.hhs.gov



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Expert Response to Questions

Date: August 18, 2023

Expert Reviewer: Michel D Janda

Expertise: Stereotaxic

Applicable Review Guide (if used): Not Applicable

Submission # K231850

Applicant: Globus Medical Inc

Device Trade Name: QUARTEX®
Occipito-Cervico-Thoracic Spinal
System ExcelsiusGPS® Instruments

Optional Classification Information:

Pro Code(s): NKG, KWP, OLO **Class:** II **Reg #:**
888.3075

Reg Name: Posterior Cervical
Screw System

Rx/OTC: Rx

I. Expert Review Summary

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

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(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Table (Doc#: 04504.02.03)		
Expert Sign-Off	Michel D. Janda -S	Digitally signed by Michel D. Janda -S Date: 2023.08.18 17:44:20 -04'00'



Valley Forge Business Center
2560 General Armistead Avenue Audubon, PA 19403
Phone: 610.930.1800 Fax: 610.930.2042
Order Fax: 610.930.2041
www.globusmedical.com

June 22, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

JUN 23 2023

RECEIVED

Re: QUARTEX Additional Implants Premarket Notification

K231850

Dear Sir/Madam,

Globus Medical Inc. hereby submits this **Traditional 510(k)** to request clearance for **QUARTEX Additional Implants**, which are line extensions to the previously cleared QUARTEX Occipito-Cervico-Thoracic Spinal System, as well as additional instruments for use with ExcelsiusGPS or ExcelsiusHub. These devices are considered Class II under panel code 87 which is with the same classification regulation as the predicate devices. In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, this submission constitutes a Premarket Notification for QUARTEX Additional Implants. There have been no prior submissions for this device. An eCopy is enclosed. A draft Refuse to Accept checklist is included for convenience.

Documentation is provided to support a claim of substantial equivalence to commercially available predicate devices, including the QUARTEX system. The intent to market this device and the information contained in this submission are considered proprietary, confidential, and protected from public disclosure in accordance with the provisions for confidentiality under 21 CFR §807.95 and other applicable provisions of the law.

Globus believes that the information contained in this submission is sufficient for the agency to find that the subject implants are substantially equivalent to the predicate devices. If additional information is required, please contact me at (610) 930-1800 (b)(6) or by email at (b)(6). An alternate contact, Kelly Baker, PhD, Senior Vice President of Regulatory and Clinical Affairs, may be reached at (610) 930-1800 (b)(6) or by email at (b)(6).

Sincerely,

(b)(6)

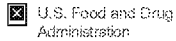
Jeremiah Antonacci, PhD
Group Manager, Regulatory Affairs
Globus Medical, Inc.

Hello Jennifer,

Thank you for agreeing to speak with us today. I have confirmed receipt of your redlined and clean copies. I will review this information accordingly and get back to you if we have further questions.

Have a great evening,
Michael

Michael Molyneaux-Francis
General Engineer / Lead Reviewer
Extracolumar Spinal Devices Team
CDRH / OPEQ / OHT6 / DHT6B



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From: Jennifer Antonacci (b)(6)
Sent: Wednesday, March 13, 2024 5:38 PM
To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231850/S001 - Interactive Requests

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.

Hi Michael,

Thank you again for today's call. I appreciate you and Colin taking the time to meet with me to discuss your questions. Please see attached for a (b)(4)

(b)(4)

Please let me know if you have any further questions.

Kind regards,
Jennifer



Jennifer Antonacci, Ph.D.
Senior Group Manager, Regulatory Affairs

Phone: 610-930-1800 ext (b)(6) **Fax:** 610-930-2042

Globus Medical, Inc.
2560 General Armstrong Ave. Audubon, PA 19403

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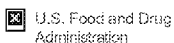
From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Sent: Wednesday, March 13, 2024 1:42 PM
To: Jennifer Antonacci (b)(6)
Subject: [External Sender] RE: K231850/S001 - Interactive Requests

Hello Jennifer,

Would you be available for a quick call between 3:00pm to 3:30pm today?

Thank you,
Michael

Michael Molyneaux-Francis
General Engineer / Lead Reviewer
Extracolumar Spinal Devices Team
CDRH / OPEQ / OHT6 / DHT6B



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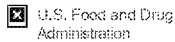
From: Molyneaux-Francis, Michael
Sent: Wednesday, March 13, 2024 1:11 PM
To: Jennifer Antonacci (b)(6)
Subject: RE: K231850/S001 - Interactive Requests

Hello Jennifer,

As usual, thank you for your quick actions. I will review with my team and get back to you if there are any further issues.

Thank you,
Michael

Michael Molyneaux-Francis
General Engineer / Lead Reviewer
Extracolumar Spinal Devices Team
CDRH / OPEQ / OHT6 / DHT6B



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From: Jennifer Antonacci (b)(6)
Sent: Wednesday, March 13, 2024 12:57 PM
To: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231850/S001 - Interactive Requests

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Hi Michael,

Thank you for your email. Please see attached for our responses to your March 12th interactive questions.

(b)(4)

Please let me know if you have any further questions or would like to discuss anything directly on a call.

Kind regards,
Jennifer



Jennifer Antonacci, Ph.D.
Senior Group Manager, Regulatory Affairs
Phone: 610-930-1860 (b)(6) **Fax:** 610-930-2042
Globus Medical, Inc.
2560 General Armstrong Ave. Audubon, PA 19403

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From: Molyneaux-Francis, Michael <Michael.Molyneaux-Francis@fda.hhs.gov>
Sent: Tuesday, March 12, 2024 3:26 PM
To: Jennifer Antonacci (b)(6)
Subject: [External Sender] K231850/S001 - Interactive Requests
Importance: High

Hello Jennifer,

I have come across several issues pertaining to (b)(4). Please respond to the below-mentioned interactive requests by **end-of-day, Wednesday, March 13th, 2024**. Let me know if this date is not acceptable. The interactive requests are as follows:

(b)(4)

(b)(4)

Please reach out if you seek additional information or have further questions. I will let you know if further issues arise.

Respectfully,
Michael

Michael Molyneux-Francis, FE
General Engineer / Lead Reviewer

Extracolumbar Spinal Devices Team
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-403-5178
Michael.Molyneux-Francis@fda.hhs.gov

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