March 13, 2019

Synthes (USA) Products LLC
Fredy Varela
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K183472
Trade/Device Name: DePuy Synthes Porous Polyethylene Implants and Titanium Wires Portfolio - MR Conditional
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, GAQ
Dated: December 11, 2018
Received: December 14, 2018

Dear Mr. Varela:

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 devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Digitally signed by David Krause -S
Date: 2019.03.13 13:12:50 -04'00'

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183472

Device Name
DEPUY SYNTHES POROUS POLYETHYLENE IMPLANTS – MR CONDITIONAL

Indications for Use *(Describe)*
The DePuy Synthes Porous Polyethylene Implants are intended for use in non-load bearing applications in craniofacial reconstruction, cosmetic surgery, and repair of craniofacial trauma.

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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183472

Device Name

DEPUY SYNTHES TITANIUM WIRE – MR CONDITIONAL

Indications for Use *(Describe)*

The DePuy Synthes Titanium Wire is indicated for use in soft tissue approximation and/or ligation, canthoplasty, canthopexy and/or canthal tendon repair.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183472

Device Name

DEPUY SYNTHES TITANIUM WIRE WITH BARB – MR CONDITIONAL

Indications for Use *(Describe)*

The DePuy Synthes Titanium Wire With Barb is indicated for use in soft tissue approximation and/or ligation, canthoplasty, canthopexy and/or canthal tendon repair.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Fredy Varela
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-5883
Email: fvarela2@its.jnj.com

Alternate Contact:
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Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Name of Device: DEPUY SYNTHES POROUS POLYETHYLENE IMPLANTS – MR Conditional

Classification Name(s): Surgical Mesh

Regulatory Class: Class II; 878.3300

Product Code(s): FTM

1.3. Predicate Devices

K051879 – Synthes Porous Polythylene Implants
K040364 - Medpor Craniofacial Implants with Embedded Titanium
K952677 - Medpor Barrier Surgical Implant Biomaterial
K832283 - Medpor Surgical Implants
K022665 - ePor Porous HDPE Surgical Implants

1.4. Device Description

The DePuy Synthes Porous Polyethylene Implants consist of porous/smooth implant sheets with or without titanium.

1.5. Indications for Use

The DePuy Synthes Porous Polyethylene Implants are intended for use in non-load bearing applications in craniofacial reconstruction, cosmetic surgery, and repair of craniofacial trauma.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DEPUY SYNTHES POROUS POLYETHYLENE IMPLANTS. The intended use and technological characteristics of the devices remain unchanged.

1.7. Performance Testing

Non-clinical testing results are provided to support the conditional safety of the DEPUY SYNTHES POROUS POLYETHYLENE IMPLANT AND TITANIUM WIRE PORTFOLIO in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14), torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07).

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

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1.2. Device

Name of Device: DEPUY SYNTHES TITANIUM WIRE – MR Conditional

Classification Name(s): Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Regulatory Class: Class II; 878.4495

Product Code(s): GAQ

1.3. Predicate Devices

K041333 - Synthes Titanium Wire
Ethilon™ Nylon Suture

1.4. Device Description

The DePuy Synthes Titanium Wire is a nonabsorbable, monofilament, sterile surgical wire composed of commercially pure titanium. The titanium wire is available in a length of 500mm with different gauge sizes, and is available with or without a permanently attached stainless steel needle.

1.5. Indications for Use

DePuy Synthes Titanium Wire is indicated for use in soft tissue approximation and/or ligation, canthoplasty, canthopexy and/or canthal tendon repair.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DEPUY SYNTHES TITANIUM WIRE. The intended use and technological characteristics of the devices remain unchanged.

1.7. Performance Testing

Non-clinical testing results are provided to support the conditional safety of the DEPUY SYNTHES POROUS POLYETHYLENE IMPLANT AND TITANIUM WIRE PORTFOLIO in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14), torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07).

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

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1.2. Device

Name of Device: DEPUY SYNTHES TITANIUM WIRE WITH BARB – MR Conditional

Classification Name(s): Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Regulatory Class: Class II; 878.4495

Product Code(s): GAQ

1.3. Predicate Devices

K042606 – Synthes Titanium Wire
K041333 – Synthes Titanium Wire

1.4. Device Description

The DePuy Synthes Titanium Wire with Barb is a nonabsorbable, monofilament, sterile surgical wire with an attached barb. The 28 gauge titanium wire with barb is available in a length of 538mm, and has a permanently attached stainless steel needle.

1.5. Indications for Use

The Depuy Synthes Titanium Wire With Barb is indicated for use in soft tissue approximation and/or ligation, canthoplasty, canthopexy and/or canthal tendon repair.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DEPUY SYNTHES TITANIUM WIRE WITH BARB. The intended use and technological characteristics of the devices remain unchanged.

1.7. Performance Testing

Non-clinical testing results are provided to support the conditional safety of the DEPUY SYNTHES POROUS POLYETHYLENE IMPLANT AND TITANIUM WIRE PORTFOLIO in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14), torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07).

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.