July 29, 2022

Depuy Synthes Spine, Inc.
Catherine Kilshaw
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142587
Trade/Device Name: DePuy Synthes Spine Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II)
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: MDI

Dear Catherine Kilshaw:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 18, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
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 & HUMAN SERVICES

Public Health Service

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

November 18, 2014

DePuy Synthes Spine
Ms. Catherine Kilshaw
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142587
Trade/Device Name: DePuy Synthes Spine Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II)
Regulatory Class: Unclassified
Product Code: MDI
Dated: September 12, 2014
Received: September 15, 2014

Dear Ms. Kilshaw:

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 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

Indications for Use

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

510(k) Number *(if known)*
K142587

Device Name
DePuy Synthes Spine Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II)

Indications for Use *(Describe)*
The VEPTR/VEPTR II device is indicated for skeletally immature patients with severe, progressive spinal deformities and/or three dimensional deformity of the thorax associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis.

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

Date Prepared: October 24, 2014

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

Contact Person: Catherine Kilshaw
Sr. Regulatory Affairs Associate
Telephone: (508) 880-8412
Fax: (508) 828-3797

Trade Name: DePuy Synthes Spine Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II)

Device Class: II

Product Code: MDI

Common Name: Prosthesis, Rib Replacement

Classification Name: Unclassified

Regulation Number: Pre-Amendment Unclassified

Primary Predicate Device: Medtronic CD HORIZON® Growth Rod Conversion Set (K133904)
Additional Predicate Devices: Medos Sarl ISOLA® and EXPEDIUM® Growing Spine Systems (K141509)
Reference Devices: Harrington Spinal Rod System (Pre-Amendment), Vertical Expandable Prosthetic Titianium Rib VEPTR and VEPTR II (H030009)

Device Description: In children with or at risk of developing Thoracic Insufficiency Syndrome, the natural course of lung development is arrested due to constriction by the thorax. The VEPTR/VEPTR II devices mechanically stabilize and/or correct thoracic deformities to allow the chest and lungs to grow.

The VEPTR devices are attached perpendicularly to the subject's natural ribs and lumbar vertebra or pelvis. This mechanically stabilizes the chest wall and enlarges the thorax to improve respiration and lung growth. Once the VEPTR/VEPTR II device is in place, its design allows for expansion, anatomic distraction, and replacement of component parts through less invasive surgery.

The VEPTR/VEPTR II devices allow assembly in a number of different configurations. All of these configurations are required to accommodate the wide variety of anatomical deformities encountered by the clinician in treating patients with or at risk of developing Thoracic Insufficiency Syndrome.

Indications: The VEPTR/VEPTR II device is indicated for skeletally immature patients with severe, progressive spinal deformities and/or three dimensional deformity of the thorax associated with or at risk of thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis.

Materials: All VEPTR/VEPTR II components are manufactured from titanium alloy, Ti-6Al-7Nb (ASTM F1295), with the exception of the sacral S-Hook, S-Rod, and 2mm rod. The S-Hooks and S-Rods are manufactured from commercially pure titanium, CP Ti Grade 4 (ASTM F67). The 2mm rods are manufactured from commercially pure titanium, CP Ti Grade 1 (ASTM F67).

Comparison to Predicate Devices: The substantial equivalence of the subject device to the predicates identified above is based upon the similarity of intended use, design (fundamental scientific technology) materials, performance, sterility and biocompatibility.

Non-clinical Test Summary: Non-clinical testing on the VEPTR/VEPTR II devices included mechanical testing, static compressive bending and dynamic compressive bending according to the methods outlined in ASTM 1717. Results of these tests demonstrate that the VEPTR device performs in a manner substantially equivalent to the predicate device.

Clinical Test Summary: The results of the HDE (H030009) post-market follow-up demonstrate that the device can be used safely with probable benefit for the indications stated. In addition, the clinical data presented demonstrated a substantially equivalent safety and effectiveness profile as the cited predicate growing spine systems (K133904 and K1411509) for the indications presented.

Conclusion: Based upon the side-by-side predicate comparison, clinical performance data for the intended use, and pre-clinical testing, the proposed device is substantially equivalent to the predicate device.