May 23, 2019

DePuy Synthes Spine
Michelle Hughes
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K183054
Trade/Device Name: SYNMESH™ System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 22, 2019
Received: April 24, 2019

Dear Ms. Hughes:

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,

for
CAPT Raquel Peat, PhD, MPH, USPHS
Director
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

Indications for Use

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

510(k) Number *(if known)*
K183054

Device Name
SYNMESH™ System

Indications for Use *(Describe)*
The SYNMESH™ Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The SYNMESH Spacer is intended to be used with Synthes supplemental internal fixation systems. The interior of the SYNMESH Spacer can be packed with bone graft.

The SYNMESH™ System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

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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"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

A. Submitter Information

Manufacturer: Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

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

Contact Person: Michelle Hughes
325 Paramount Drive
Raynham, MA 02767
Telephone: 904-608-1262
Fax: 508-828-3797
Email: mhughe37@its.jnj.com

B. Date Prepared

April 22, 2019

C. Device Name

Trade/Proprietary Name: SYNMESH™ System

Common/Usual Name: Implant, fixation, spinal intervertebral body fixation orthosis device

Regulatory Class: Class II per 21 CFR § 888.3060

Review Panel: Orthopedic

Product Codes: MQP, spinal vertebral body replacement device

D. Primary Predicate Device Name

Synthes SynMesh Spacer System cleared on April 23, 2001 via 510(K), K003275.

E. Device Description

The purpose of this premarket notification is to obtain market clearance to add a new longer round mesh spacer to the SYNMESH™ Spacer System.

The SYNMESH System spacer is a titanium vertebral body replacement device used in conjunction with supplemental internal fixation to provide structural stability in skeletally

mature individuals following corpectomy/vertebrectomy. Different cross section sizes and heights are available to suit the individual pathology and anatomical conditions.

The SYNMESH System spacer consists of a cylindrical round or oblong mesh, end rings, standard rings and screws. The round mesh is used in pairs and is available in various diameters and heights. The oblong mesh is used individually and is also available in various cross-section sizes and heights.

F. Indications for Use

The SYNMESH™ Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The SYNMESH™ Spacer is intended to be used with the Synthes supplemental internal fixation systems. The interior of the SYNMESH ™ Spacer can be packed with bone graft.

The SYNMESH™ System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

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

The intended use, technological characteristics, and performance of the new longer SYNMESH System Spacer is consistent with those of the predicate device.

H. Materials

The SYNMESH System Spacer components are manufactured from commercially pure Titanium Grade 2 and 4 (CP-Ti) per ISO 5832-2 and ASTM F 67.

I. Performance Data

Non-clinical testing was conducted in alignment with the following standard:

- ASTM F2077-14 *Standard Test Methods for Intervertebral Body Fusion Device*

The following performance tests were evaluated, supporting substantial equivalence:

- Static Torsion
- Dynamic Torsion
- Static Compression
- Dynamic Compression
- Expulsion
- Subsidence

J. Conclusion

The subject device, SYNMESH™ Spacer System is substantially equivalent to the predicate device because the intended use and fundamental scientific technology remain unchanged.