April 4, 2019

Medtronic Sofamor Danek USA, INC.
Ankit Shah
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K183197
Trade/Device Name: PYRAMESH™ Implant System
Regulation Number: 21 CFR 888.3060
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MQP
Dated: March 8, 2019
Received: March 7, 2019

Dear Mr. Shah:

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,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183197

Device Name
PYRAMESH™ Implant System

Indications for Use *(Describe)*
The PYRAMESH™ implants are for use in the thoracolumbar spine (T1 to L5) to replace and restore the height of a diseased or damaged vertebral body caused by tumor and/or fracture. When used for Spinal Indications PYRAMESH™ implants is intended to be used with supplemental fixation. Allograft or autograft material may be used at the surgeon's discretion.

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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K183197
510(k) SUMMARY
MEDTRONIC SOFAMOR DANEK
PYRAMESH™ Implant System

I. **Submitter**

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Ankit K. Shah
Principal Regulatory Affairs Specialist
Phone: (901) 344-1272

Date Prepared: November 9, 2018

II. Device

Name of Device: PYRAMESH™ Implant System

Classification Names: Spinal vertebral body replacement device (21 CFR 888.3060)

Class: Class II

Product Code: MQP

III. Predicate Devices:

Primary Predicate

SPINAL™ Mesh System

Predicate 1: K011406 (S.E. 12/27/2001)

Additional Predicates:

T2 Spinal System

Predicate 2: K091883 (S.E. 09/21/2009)

VERTE-STACK™ Spinal System

Predicate 3: K052931(S.E. 11/16/2005)

SynMesh System

Predicate 4: K041389 (S.E. 10/01/2004)

The predicates have not been subject to a design related recall.

IV. Description:

The PYRAMESH™ implant device is a cylindrically-shaped implantable device with open ends and a hollow core throughout its longitudinal axis. Pyramid shaped openings are built into the wall of the device. These openings and the hollow core allow grafting material to be placed inside the device to help achieve a solid fusion. The contoured ends of the PYRAMESH™ implant serve to grip the superior and inferior end plates when used for spinal indications, thus allowing expulsion resistance.

The device is made from commercially pure titanium and titanium alloy and is available in various sizes to match patients' anatomical requirements.

When used as a vertebral body replacement device, the PYRAMESH™ implant is intended to be used with supplemental spinal fixation systems cleared for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

V. Indications for Use:

The PYRAMESH™ implants are for use in the thoracolumbar spine (T1 to L5) to replace and restore the height of a diseased or damaged vertebral body caused by tumor and/or fracture. When used for spinal indications, PYRAMESH™ implants are intended to be used with supplemental fixation. Allograft or autograft material may be used at the surgeon's discretion.

VI. Comparison of Technological Characteristics with the Predicate Devices:

The subject PYRAMESH™ implants have the same indications, intended use, fundamental scientific technology, materials, and sterilization method as the previously FDA cleared predicate devices.

VII. **Performance Data:**

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject PYRAMESH™ Implant System implants are permanent implants (> 30 days) and will be classified as body contacting devices according to FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The subject instruments are manufactured from identical materials as the primary predicate, in accordance with the following standards:

- ASTM F67: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ASTM F136: Standard Specification for Wrought Titanium – 6Aluminum – 4Vanadium ELI (Extra-Low-Interstitial) Alloy for Surgical Implants

Mechanical Testing

Non-clinical mechanical testing was performed for the subject implants. The subject implants are identical to the predicate devices in terms of fundamental technology, intended use and indications for use. The design verification testing conducted was completed in accordance with ASTM Draft Standard F-04.25.0202 (Static Expulsion) and ASTM F2077 Test Methods For Intervertebral Body Fusion Devices (Static Compression, Static Torsion, Compression Fatigue and Torsion Fatigue).

The subject implants were also tested for the magnetic resonance imaging (MRI) safety and compatibility as per:

- ASTM F2052 - "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"

- ASTM F2213 - "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment"
- ASTM F2119 - "Standard test method for evaluation of MR image artifacts from passive implants"
- ASTM F2182 - "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging"
- ASTM F2503 - "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment"

VIII. Conclusion:

Based on the supporting information provided in this pre-market notification, the subject PYRAMESH™ Implant System is substantially equivalent to the predicate SPINAL™ Mesh System, K011406 (S.E. 12/27/2001), T2 Spinal System, K091883 (S.E. 09/21/2009), VERTE-STACK™ Spinal System, K052931(S.E. 11/16/2005) and SynMesh System, K041389 (S.E. 10/01/2004).