DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ankit K. Shah
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

March 7, 2016

Re: K160418
Trade/Device Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 15, 2016
Received: February 16, 2016

Dear Ankit 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. 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

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" (21CFR 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,

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

Indications for Use

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

510(k) Number *(if known)*
K160418

Device Name
PERIMETER® Interbody Fusion Device

Indications for Use *(Describe)*
The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral, and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

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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PERIMETER® Interbody Fusion Device
510(k) Summary
February 2016

I. Submitter:

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Telephone: (901)396-3133
Fax: (901) 346-9738

Contact: Ankit K. Shah
Senior Regulatory Affairs Specialist

Date Prepared: February 25, 2016

II. Device

Name of Device: PERIMETER® Interbody Fusion Device

Common or Usual Name: Intervertebral body fusion device (21 CFR 888.3080)

Classification Name: Intervertebral fusion device with bone graft, lumbar

Regulatory Class: Class II

Product Code: MAX

III. Predicate Device

K111525 (S.E. 08/24/2011) PERIMETER® Interbody Fusion Device – Primary Predicate

K090353 (S.E. 09/29/2009) – PERIMETER® Interbody Fusion Device - Additional Predicate

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

IV. Device Description:

The PERIMETER® Interbody Fusion Device consists of interbody cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation.

V. Indications for Use:

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral, and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VI. Comparison of Technological Characteristics with Predicate Device

The subject PERIMETER® Interbody Fusion Devices have identical: indications for use, intended use, design, material (Titanium Alloy per ASTM F136), levels of attachment and fundamental scientific technology as the PERIMETER® Interbody Fusion Devices predicate previously cleared by the FDA in K111525 (S.E. 08/24/2011). Additionally, the new PERIMETER® Interbody Fusion Devices are provided sterile identical to that of the predicate 2 devices found in K090353 (S.E. 09/29/2009). The purpose of this submission is to include additional interbody cages manufactured from medical grade titanium alloy (Ti-6Al-4V ELI) that are packaged sterile via gamma irradiation.

Instruments (trials) are also being added to provide appropriate sizing options for implant sizes already cleared in predicate 510(k)s. The non-sterile trials are manufactured using stainless steel and have identical indications for use, intended use, materials and design to the instruments cleared under the predicate 510(k)s.

VII. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

Identical to the primary predicate devices the implants in the subject PERIMETER® Interbody Fusion Device are made using Titanium alloy.

The non-sterile instruments are manufactured using stainless steel and are identical to the materials used for the instruments cleared under predicate submissions.

The titanium alloy and stainless steel material used for the subject PERIMETER® Interbody Fusion Devices implants and instruments (trials) have a long clinical history of safe and effective use in similar commercially available medical devices. Therefore, no additional biocompatibility testing is required.

Mechanical Testing

In accordance with, Guidance for Industry and FDA Staff – Spinal System - 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. It was determined that subject devices do not represent a new worst case. Therefore, an engineering rationale was used to demonstrate substantial equivalence. As a new worst case has not been indicated and an engineering rationale was deemed adequate to prove equivalence to the predicate device, no additional mechanical testing is required.

VIII. Conclusion

Based on a risk analysis, engineering rationale, and additional supporting documentation provided in this pre-market notification, the subject PERIMETER® Interbody Fusion Devices (implants and instruments) are as safe and effective as the following predicates K111525 (S.E. 08/24/2011) PERIMETER® Interbody Fusion Device – Primary Predicate and K090353 (S.E. 09/29/2009) – PERIMETER® Interbody Fusion Device - Predicate 2.