DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 2, 2016

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

Re: K153438
Trade/Device Name: PERIMETER® C (Titanium) Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 8, 2016
Received: February 10, 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,

Lori A. Wiggins -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)*
K153438

Device Name
PERIMETER® C (Titanium) Spinal System

Indications for Use *(Describe)*
The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

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® C (Titanium) Spinal System
510(k) Summary
January 2016

I. Submitter:

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

Contact: Ankit K. Shah
Senior Regulatory Affairs Specialist

Date Prepared: January 6, 2016

II. Device

Name of Device: PERIMETER® C (Titanium) Spinal System

Common or Usual Name: Intervertebral body fusion device

Classification Name: Intervertebral fusion device with bone graft, cervical: 21 CFR 888.3080

Regulatory Class: Class II

Product Code: ODP

III. Predicate Device

K132584 (S.E. 12/04/2013) PERIMETER® C Spinal System – Primary Predicate

K133645 (S.E. 01/03/2014) – PERIMETER® C Spinal System - Additional Predicate

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

IV. Device Description:

The PERIMETER® C (Titanium) Spinal System consists of spacers/cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. Additionally, this implant has six degrees of lordosis and the superior and inferior surfaces of the implant

are designed with teeth which interact with the surface of the vertebral endplates to aid in resisting expulsion. The hollow geometry of the implants allows them to be packed with autogenous bone graft and is to be used with supplemental fixation in all procedures.

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.

V. Indications for Use:

The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

VI. Comparison of Technological Characteristics with Predicate Device

The subject PERIMETER® C (Titanium) Spinal System Devices have identical: indications for use, intended use, design, material (Titanium Alloy per ASTM F136), sterilization methods, levels of attachment and fundamental scientific technology as the PERIMETER® C Spinal System predicate previously cleared by the FDA in K132584 (S.E. 12/04/2013). Additionally, the new PERIMETER® C (Titanium) Spinal System Devices are provided sterile identical to that of the predicate 2 devices found in K133645 (S.E. 01/03/2014).

VII. Performance Data

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

Biocompatibility

The biocompatibility evaluation for the PERIMETER® C (Titanium) Spinal System devices was conducted in accordance with 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" issued April, 23, 2013.

The subject PERIMETER® C (Titanium) Spinal System intervertebral body fusion devices are permanent implants and will be classified as permanent, >30 day body contact according to with 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 intervertebral body fusion devices are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standard:

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

The titanium alloy material used for the subject PERIMETER® C (Titanium) Spinal System intervertebral body fusion devices has a long clinical history of safe and effective use in similar 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. 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 the pre-market notification, the subject PERIMETER® C (Titanium) Spinal System intervertebral body fusion devices are as safe and effective as the following predicates: K132584 (S.E. 12/04/2013) – Primary Predicate and K133645 (S.E. 01/03/2014) - Predicate 2.