



Food and Drug Administration
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January 19, 2016

Medtronic Sofamor Danek
Sneh Pingle
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K153373

Trade/Device Name: CORNERSTONE[®] PSR Cervical Fusion System, PERIMETER[®]
C Spinal System, PEEK PREVAIL[®] Cervical Interbody Device

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: ODP, OVE

Dated: November 20, 2015

Received: November 23, 2015

Dear Sneh Pingle:

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

Indications for Use

510(k) Number (if known)

K153373

K153373

Page 1 of 3

Device Name

CORNERSTONE® PSR Cervical Fusion System

Indications for Use (Describe)

The CORNERSTONE® PSR device is indicated for 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. 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. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)

K153373

K153373

Page 2 of 3

Device Name

PERIMETER® C 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/or allogenic bone graft comprised of cancellous and/or corticocancellous 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)

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Indications for Use

510(k) Number (if known)

K153373

K153373

Page 3 of 3

Device Name

PEEK PREVAIL® Cervical Interbody Device

Indications for Use (Describe)

The PEEK PREVAIL® Cervical Interbody Device is indicated 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. 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. The PEEK PREVAIL® Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL® Cervical Interbody Device implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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Cervical Anterior Spacers not for sale to the general public. If you are a federal agency, a contractor of a federal agency, a 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

Medtronic Sofamor Danek

CORNERSTONE® PSR Cervical Fusion System, PEEK PREVAIL® Cervical Interbody Device and PERIMETER® C Spinal System

I. SUBMITTER

Medtronic Sofamor Danek USA, Inc.
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Memphis, Tennessee 38132
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Fax: (901) 346-9738

Contact Person: Sneh Pingle, Regulatory Affairs Specialist
Date Prepared: 14 January 2016

II. DEVICE

Name of Devices: CORNERSTONE® PSR Cervical Fusion System
PERIMETER® C Spinal System
PEEK PREVAIL® Cervical Interbody Device
Common or Usual Name: Cervical Intervertebral Fusion Device

Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

Regulatory Class: II

Product Code: ODP, OVE

III. PREDICATE DEVICE

Primary Predicate:

- ANATOMIC PEEK Cervical Fusion System (K130177, SE 09/23/2013)

Additional Predicate Devices:

- CORNERSTONE® PSR Cervical Fusion System (K111264, SE 10/12/2011)
- PERIMETER® C Spinal System (K100967, SE 08/05/2011; K132584, SE 12/04/2013)
- PEEK PREVAIL® Cervical Interbody Devices (K073285, SE 05/15/2008; K094042, SE 06/30/2010)

IV. DEVICE DESCRIPTION

CORNERSTONE® PSR Cervical Fusion System

The CORNERSTONE® PSR Cervical Fusion System consists of cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in cervical fusion procedures. The CORNERSTONE® PSR device is to be used with supplemental instrumentation, and is to be implanted via an open, anterior approach.

The CORNERSTONE® PSR devices are manufactured from medical grade polyetheretherketone (PEEK) material with tantalum or titanium alloy (Ti-6Al-4V) pin markers. The PEEK material used in the subject interbody cage conforms to ASTM F2026 “Standard Specification for polyetheretherketone (PEEK) Polymers for Surgical Implant Applications”, the titanium alloy material used conforms to ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)” and the tantalum material used conforms to ASTM F560 “Standard Specification for Unalloyed Tantalum for Surgical Implant Applications”.

PERIMETER® C Spinal System

The PERIMETER® C Spinal System consists of spacers 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/or allogenic bone graft comprised of cancellous

and/or corticocancellous bone graft and is to be used with supplemental fixation in all procedures. PERIMETER® C Spinal System is used with instrumentation that enables the surgeon to implant the devices via an open, anterior approach.

The subject PERIMETER® C devices are manufactured from medical grade titanium alloy (Ti-6Al-4V) or polyetheretherketone (PEEK) material with tantalum pin markers. The PEEK material used in the subject interbody cage conforms to ASTM F2026 “Standard Specification for polyetheretherketone (PEEK) Polymers for Surgical Implant Applications”, the titanium alloy material used conforms to ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)” and the tantalum material used conforms to ASTM F560 “Standard Specification for Unalloyed Tantalum for Surgical Implant Applications”.

PEEK PREVAIL® Cervical Interbody Device

The PEEK PREVAIL® Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is “I-Beam” shaped with a two screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The subject PEEK PREVAIL® Cervical Interbody device implant is manufactured from medical grade polyetheretherketone (PEEK) material and contains tantalum radiopaque markers. The subject device also contains a Nitinol screw locking mechanism and uses bone screws made of grade titanium alloy (Ti-6Al-4V). The PEEK material used in the subject interbody cage conforms to ASTM F2026 “Standard Specification for polyetheretherketone (PEEK) Polymers for Surgical

Implant Applications”, the titanium alloy material used for bone screws conforms to ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)”, the tantalum material used conforms to ASTM F560 “Standard Specification for Unalloyed Tantalum for Surgical Implant Applications” and the Nitinol material used conforms to ASTM F2063 “Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants”.

V. INDICATIONS FOR USE

CORNERSTONE® PSR Cervical Fusion System

The CORNERSTONE® PSR device is indicated for 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. 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. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

PERIMETER® C Spinal System

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/or allogenic bone graft

comprised of cancellous and/or corticocancellous bone graft and supplemental fixation and implanted via an open, anterior approach.

PEEK PREVAIL® Cervical Interbody Device

The PEEK PREVAIL® Cervical Interbody Device is indicated 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. 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. The PEEK PREVAIL® Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL® Cervical Interbody Device implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

VI. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for both the subject and predicate devices is cervical interbody fusion to provide correction and stabilization during intervertebral body fusion procedures. The subject devices are all manufactured from the same materials noted in the previously cleared predicate and referenced devices. Both the subject and predicate devices operate on the usage of PEEK/ Titanium Alloy cages inserted into the disc space along with graft material to facilitate fusion at single or multiple levels in the cervical spine. The predicate and subject devices consist of both interbody cages which include internal fixation screws and interbody cages which must be used with supplemental fixation. Both the subject and predicate devices are surgically implanted via an anterior approach for the same patient population. The purpose of this 510(k) bundled submission is to expand the indications to allow these interbody cages to be used with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as a graft material option. With the exception of the

inclusion of allograft to the modified indications, there have been no changes to subject systems, and they are therefore substantially equivalent to the predicate ANATOMIC PEEK.

VII. DISCUSSION OF SUPPORTING RETROSPECTIVE CLINICAL DATA AND NON-CLINICAL TESTING

Published retrospective clinical data for the cervical interbody fusion devices were provided in support of this application. The clinical data demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above poses no new risks to patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

VIII. CONCLUSIONS

The design features, materials used, manufacturing and sterilization methods are equivalent to the previously cleared CORNERSTONE® PSR, PEEK PREVAIL®, and PERIMETER® C cervical fusion system components with the exception of broadening the indications to include the aforementioned use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative graft material. The expanded indications sought in this application are identical to those granted to the ANATOMIC PEEK Spinal System in K130177 (SE 09/23/2013).

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