JAN - 3 2014

510(k) SUMMARY
MEDTRONIC Sofamor Danek
MRI Update for PEEK Interbody Fusion Devices
November 26, 2013

I. **Company:**

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Contact:**

Becky Ronner
Senior Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738

III. **Proprietary Trade Name:**

Cervical Interbody Fusion Devices
PERIMETER® C Spinal System (PEEK)
Lumbar Interbody Fusion Devices
CAPSTONE® PEEK Spinal System
CAPSTONE® L Spinal System (PEEK)
PERIMETER® Interbody Fusion Device (PEEK)

IV. **Common &Classification Names:**

Cervical & Lumbar Interbody Fusion Devices

Class: II

Product Code:

ODP (21 CFR 888.3080)	PERIMETER® C Spinal System (PEEK)
MAX (21 CFR 888.3080)	CAPSTONE® PEEK Spinal System CAPSTONE® L Spinal System (PEEK) PERIMETER® Interbody Fusion Device(PEEK)

V. **Description:**

a. **PERIMETER® C Spinal System (PEEK)**

The PERIMETER® C Spinal System consists of PEEK spacers with tantalum markers 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, 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.

b. CAPSTONE® PEEK Spinal System (PEEK)

The CAPSTONE® Spinal System consists of PEEK cages with tantalum markers 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. Additionally, 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.

c. CAPSTONE® L Spinal System

The CAPSTONE® L Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. Additionally, 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.

d. PERIMETER® Interbody Fusion Device(PEEK)

The PERIMETER® Interbody Fusion Device consists of PEEK cages with tantalum markers 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. Additionally, 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. The PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation.

VI. Indications for Use:

a. PERIMETER® C Spinal System (PEEK)

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.

b. CAPSTONE® PEEK Spinal System

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two 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.

Additionally, the CAPSTONE® Spinal System is indicated in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

c. CAPSTONE® L Spinal System (PEEK)

The CAPSTONE® L Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CAPSTONE® L Spinal System is used for patients diagnosed 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 minimally invasive lateral approach.

d. PERIMETER® Interbody Fusion Device(PEEK)

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.

VII. Summary of the Technological Characteristics:

The purpose of this bundled 510(k) application is to provide MRI safety labeling for the subject devices, while also providing MRI technologists with a method of concluding whether an MRI scan can be performed on the device and specific instructions on how to perform the scan. The systems in this 510(k) submission have been determined to be MR conditional per ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The MRI safety labeling that is being proposed has previously been cleared by FDA in submission K122037 for the following PEEK Interbody Fusion Devices:

- ANATOMIC PEEK Cervical Fusion System
- CORNERSTONE® PSR Spinal System
- CAPSTONE CONTROL™ Spinal System
- CLYDESDALE® Spinal System
- CRESCENT® PEEK Spinal System
- SOVEREIGN® Spinal System
- TELAMON® PEEK Vertebral Body Spacer

All the subject devices within this bundled submission have the same fundamental technology. They are intended to provide correction and stabilization during intervertebral body fusion procedures for treatment of degenerative disc disease. They are all manufactured from the same PEEK and tantalum materials and have been designed to be used with autogenous bone graft. There have been no changes to the overall design, to the material or the indications of the subject devices and are therefore substantially equivalent to their predicates.

The subject devices are substantially equivalent to the devices and 510(k)s listed below:

a. PERIMETER® C Spinal System (PEEK)
   - K100967 August 5th, 2011

b. CAPSTONE® PEEK Spinal System Implants
   - K073291 April 24th, 2008
   - K121760 August 29th, 2012
   - K123027 July 25th, 2013

c. CAPSTONE® L Spinal System Implants(PEEK)
   - K123978 April 9th, 2013

d. PERIMETER® Interbody Fusion Device (PEEK) Implants
   - K090353 September 29th, 2009

e. PEEK Interbody MRI Update (includes worst case for MRI for PEEK Interbody Devices)
   - K122037 March 22nd, 2013

IX. Discussion of Non-Clinical Testing:

In accordance FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" testing has been completed on the worst case implants. The following testing has been completed and provided a determination that the subject devices in this 510(k) submission are MR Conditional:

- 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"

X. Conclusion:

Non-clinical testing in accordance with the standards listed above was completed along with a risk analysis. Based on the test results and additional

supporting documentation provided within this pre-market notification, Medtronic believes that the subject devices demonstrate substantial equivalence to the listed predicate device and should be labeled as MR Conditional in accordance with ASTM F2503 – "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Becky Ronner
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133645
Trade/Device Name: PERIMETER® C Spinal System, CAPSTONE® PEEK Spinal System, CAPSTONE® L Spinal System, PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: November 26, 2013
Received: November 27, 2013

Dear Ms. Ronner:

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 Part 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(If known)*
K133645

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 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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Hwang, Ph.D.

Division of Orthopedic Devices

PSC Publishing Services (301) 443-6740 EF

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
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510(k) Number *(If known)*
K133645

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133645

Device Name
CAPSTONE® PEEK Spinal System

Indications for Use *(Describe)*
The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two 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.

Additionally, the CAPSTONE® Spinal System is indicated in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133645

Device Name
CAPSTONE® L Spinal System

Indications for Use *(Describe)*
The CAPSTONE® L Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CAPSTONE® L Spinal System is used for patients diagnosed 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 minimally invasive lateral 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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