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TELAMON® PEEK Spinal System
Interbody Fusion Device
510(k) Summary
February 2011

I. Company: **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Regina Holmes**
Senior Regulatory Affairs Specialist

II. Proprietary Trade Name: TELAMON® Spinal System

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Product Code: MAX (21 CFR 888.3080)

Common Name: Interbody Fusion Device

III. Product Description

The subject TELAMON® PEEK Spinal System consists of vertebral body spacers which can be inserted between two lumbar or lumbo-sacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implant allows them to be packed with autogenous bone graft material. The TELAMON® PEEK Spinal System also includes instrumentation that enables the surgeon to implant the devices via an open or a minimally invasive posterior approach.

The device sizes are available in various height and lordotic angle options. The implant devices are manufactured from medical grade polyetheretherketone (PEEK – OPTIMA® LT1) per ASTM F2026 and also contain tantalum markers per ASTM F-560 so that the position of the implant can be determined on X-ray or other imaging.

IV. Indications for Use

The TELAMON® PEEK Spinal System is indicated for interbody fusion with autogenous bone graft in 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 are to be used with autogenous bone graft and are intended for bilateral placement in the lumbar spine. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

V. Performance Data

The following pre-clinical studies were conducted using worst case TELAMON® devices: static and dynamic compression; and static and dynamic compression shear per ASTM F2077-03; and subsidence per ASTM F2267-04. The results of these studies were found to be substantially equivalent to legally marketed devices.

VI. Substantial Equivalence

Documentation was provided which demonstrated that the subject device is substantially equivalent to the following currently marketed devices: VERTE-STACK® Spinal System (K031780); CAPSTONE® Spinal System (K073291); CRESCENT™ Spinal System (K094025); LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015); RAY® Threaded Fusion Cage (P950019); and Brantigan Lumbar I/F CAGE® (P960025).

VII. Conclusion

When compared to the predicate devices, it was determined that the subject device is substantially equivalent based on the following factors:

- The device designs are similar in shape, size, and footprint range.
- The devices share the same intended use.
- The devices are manufactured from the same material and under go the same sterilization methods.
- The results of mechanical testing are comparable to the predicates and demonstrate that the subject device is as safe and effective as other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Medtronic Sofamor Danek
% Ms. Regina Holmes
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K110562
Trade/Device Name: TELAMON® PEEK Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 13, 2011
Received: October 14, 2011

Dear Ms. Holmes:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110562

Device Name: TELAMON® PEEK Spinal System

Indications for Use:

The TELAMON® PEEK Spinal System is indicated for interbody fusion with autogenous bone graft in 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 I 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 are to be used with autogenous bone graft and are intended for bilateral placement in the lumbar spine. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110562