INTREPID™ Spinal System
510(k) Summary
March 2008 – K080083

APR 10 2008

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

Contact: **Lee Grant**
Senior Project Specialist, Regulatory Affairs

II. **Proprietary Trade Name: INTREPID™ Spinal System**

III. **Classification Name/Product Code:** Intervertebral Body Fusion Device (21 CFR 888.3080)

IV. **Product Code: MAX**

V. **Product Description**

The INTREPID™ Spinal System is a stand-alone intervertebral body fusion device, which consists of an anatomically shaped vertebral body spacer designed with a self-distracting nose. The spacer is equipped with three holes which allow for the placement of internal fixation screws. The screws are inserted through the cage and help provide stabilization and back-out resistance. The INTREPID™ spacer is manufactured from medical grade polyetheretherketone (PEEK), while the screws are manufactured from titanium alloy.

V. **Indications**

The INTREPID™ Spinal System is indicated for use 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 laparoscopic or an open anterior approach.

The INTREPID™ interbody device is intended to be used with the three titanium alloy screws which accompany the implant. If the physician chooses to use less than three, or none of the provided screws, then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability.

VI. Substantial Equivalence

Documentation, including mechanical test results was provided which demonstrated that the subject INTREPID™ Spinal System is substantially equivalent to the SynFIX-LR Spacer (K072253, SE 10/12/07, Synthes Spine), the LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015, Medtronic Sofamor Danek, Approved 9/10/03), the BAK® Cage (P950002, Zimmer Spine, Approved 7/8/03), the RAY® Threaded Fusion Cage (P950019, Stryker, Approved 9/4/03), the Lumbar I/F Cage (P960025, DePuy, Approved 3/4/05) and the PARAMOUNT Intervertebral Body Fusion Device (K072120, Innovative Spinal Technologies, SE 10/11/07).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2008

Medtronic Sofamor Danek
% Mr. Lee Grant
Senior Project Specialist, Regulatory Affairs
1800 Pyramid Place
Memphis, TN 38132

Re: K080083
Trade/Device Name: INTREDPID™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: January 8, 2008
Received: January 11, 2008

Dear Mr. Grant:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

March 2008

510(k) Number (if known): K080083

Device Name: INTREPID™ Spinal System

Indications for Use:

The INTREPID™ Spinal System is indicated for use 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 laparoscopic or an open anterior approach. The INTREPID™ interbody device is intended to be used with the three titanium alloy screws which accompany the implant. If the physician chooses to use less than three, or none of the provided screws, then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability.

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

Mark A. Pogue for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080083