K060415

SATELLITE™ SPINAL SYSTEM
510(k) Summary
February 2006

JAN - 5 2007

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

Contact: **Edward S. Chin**
Group Director, Clinical and Regulatory Affairs

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

III. **Classification Name: Orthosis, Spinal Intervertebral Fusion, Solid Sphere**

IV. **Regulation Number: Preamendment Device**

V. **Product Code: NVR**

VI. **Product Description**

The SATELLITE™ Spinal System consists of spheres manufactured from either cobalt chrome or medical grade PEEK-OPTIMA LT1, which may be implanted from L3-S1 to provide temporary stabilization in order to help promote fusion.

VII **Indications**

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

VIII **Substantial Equivalence**

The purpose of this submission was to add PEEK-OPTIMA LT1 spheres with Tantalum markers to the system. Documentation was provided which demonstrated the subject SATELLITE™ Spinal System devices to be substantially equivalent to the cobalt chrome SATELLITE™ Spinal System devices previously cleared in K051320 (SE 09/09/05).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

JAN - 5 2007

Re: K060415/S1
Trade Name: SATELLITE® Spinal System
Regulatory Class: Unclassified
Product Code: NVR
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Scifert:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

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

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060415

Device Name: SATELLITE™ Spinal System

Indications for Use:

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

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)

Barbara Quenn

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

510(k) Number K060415/c