K050484

MAY - 4 2005

BASIS™ Spinal System
Summary of Safety and Effectiveness
April 2005

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

Contact: **Richard W. Treharne, PhD**
Senior Vice President Regulatory Affairs

II. **Proposed Proprietary Trade Name: BASIS™ Spinal System**

III. **Classification Name(s)/Product Code(s):**
Classification Name: Spinal Interlaminal Fixation Orthosis, Pedicle Screw Spinal System, Spinal Intervertebral Body Fixation Orthosis (per 21 CFR Sections 888.3050, 888.3060, and 888.3070)
Product Codes: KWP, KWQ, MNH, and MNI

IV. Product Description

The BASIS™ Spinal System consists of a variety of shapes and sizes of hooks, screws and rods as well as ancillary instrument sets. The BASIS™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

BASIS™ hooks are intended for posterior use only.

The BASIS™ Spinal System implant components are made from medical grade titanium and titanium alloy. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components in the same construct.**

V. Indications

BASIS™ Screws and Hooks

The BASIS™ Spinal System is intended for posterior, non-cervical fixation for the following indications: spinal stenosis; spondylolisthesis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); trauma (i.e., fracture or dislocation); pseudarthrosis; tumor; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar, or anterior cervical system, BASIS components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

VI. Substantial Equivalence

Documentation was provided which demonstrated the BASIS™ Spinal System to be substantially equivalent to the following systems: CD HORIZON® Spinal System screws, hooks and Rods (K042025, K020709 and K981676).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Richard W. Treharne, PhD
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Re: K050484
Trade/Device Name: BASIS™ Spinal System
Regulation Number: 21 CFR 888.3070, 888.3060, 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MNI, KWQ, KWP, MNH
Dated: February 22, 2005
Received: February 25, 2005

Dear Dr. Treharne:

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

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (K050484):

Device Name: BASIS™ Spinal System

Indications For Use

BASIS™ Screws and Hooks
The BASIS™ Screws and Hooks are intended for posterior, non-cervical fixation for the following indications: spinal stenosis; spondylolisthesis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); trauma (i.e., fracture or dislocation); pseudarthrosis; tumor; and/or failed previous fusion.

BASIS™ Components
Except for hooks, when used as an anterolateral thoracic/lumbar, BASIS™ components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

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 General, Restorative, and Neurological Devices

510(k) Number K050484