TRAVERSE™ Spinal Fixation System
510(k) Summary – K062447

OCT 15 2007

September 2007

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Raphael McInnis**
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name: TRAVERSE™ Spinal Fixation System**

III. **Classification Name(s):** Spinal Interlaminal Fixation Orthosis; Spinal Intervertebral Body Fixation Orthosis; Pedicle Screw Spinal System; Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disease; Class: II; Product Code(s): KWP,MNI; and Regulation No.: 888.3050 and 888.3070

IV. **Legally Marketed Devices:** GALAXY™ 3.2 Spinal System (K043020)

V. **Description:** The TRAVERSE™ Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical and/or upper thoracic spine.

The TRAVERSE™ Spinal Fixation System is a posterior system, which consists of a variety of shapes and sizes of rods, hooks, screws and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both systems for labeling limitations.

The TRAVERSE™ Spinal Fixation System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt-chromium-molybdenum alloy. Medical grade titanium, medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or cobalt-chromium-molybdenum alloy with stainless steel in the same construct. Lastly, the offset connectors contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel.

VI. **Indications for Use**: When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the TRAVERSE™ Spinal Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Screws/Connectors

The use of screws is limited to placement in T1-T3 only. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable used with the TRAVERSE™ Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

VII. **Substantial Equivalence**: The TRAVERSE™ Spinal Fixation System is substantially equivalent to the GALAXY™ 3.2 Spinal System (K043020, SE 01/07/05). Performance bench testing performed for the TRAVERSE™ Spinal Fixation System includes compression fatigue, static compression, and static torsion. The purpose of this testing was to support substantial equivalence to the aforementioned GALAXY™ 3.2 Spinal System. The results of the testing performed on the TRAVERSE™ Spinal Fixation System were equivalent or better than the commercially available GALAXY™ 3.2 Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2007

Medtronic, Inc.
c/o Mr. Raphael McInnis
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, TN 38132

Re: K062447
Trade/Device Name: TRAVERSE™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: September 28, 2007
Received: October 1, 2007

Dear Mr. McInnis:

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" (21 CFR 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

510(k) Number (if known): K062447

Device Name: TRAVERSE™ Spinal Fixation System

Indications for Use

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the TRAVERSE™ Spinal Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Screws/Connectors

The use of screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

Titanium ATLAS™ Cable used with the TRAVERSE™ Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

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)

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

510(k) Number K062447