JUN 1 3 2003

K031533

VANTAGE™ Anterior Fixation System
510(k) Summary
May 2003

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

II. Proprietary Trade Name: VANTAGE™ Anterior Fixation System

III. Regulation Number and Product Code: 888.3050 - KWP

IV. Product Description

The VANTAGE™ Anterior Fixation System consists of a variety of shapes and sizes of plates, screws, nuts, spacers and staples, as well as ancillary products and instrument sets. The components can be locked into a variety of configurations, with each construct tailor-made for the individual case.

The purpose of this submission is to add bolts to the VANTAGE™ Anterior Fixation System.

V. Indications

Properly used, the VANTAGE™ Anterior Fixation System is intended to provide stabilization during the development of a solid spinal fusion. The specific indications are: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) pseudoarthrosis, (3) spondylolysis, (4) spinal deformation such as kyphosis and lordosis, (5) fracture, (6) unsuccessful previous attempts at spinal surgery, (7) tumor resection, (8) correction of severe instability and/or deformity when used in addition to a posterior spinal instrumentation system, (9) neoplastic disease, and/or (10) deformity associated with deficient posterior elements, such as laminectomy, spina bifida, or myelomeningocele.

VI. Substantial Equivalence

Documentation was provided which demonstrated the VANTAGE™ Anterior Fixation System to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2003

Richard W. Treharne, Ph.D.
Sr. Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K031533
Trade Name: VANTAGE™ Anterior Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: May 15, 2003
Received: May 16, 2003

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.

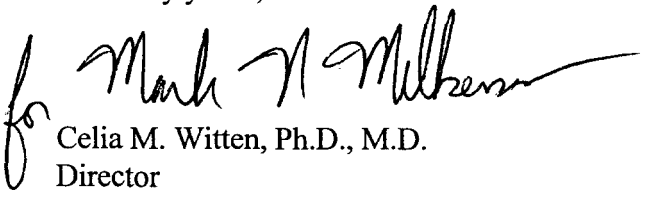
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (301) 594-4659. 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/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031533

Device Name: VANTAGE™ Anterior Fixation System

Indications for Use:

Properly used, the VANTAGE™ Anterior Fixation System is intended to provide stabilization during the development of a solid spinal fusion. The specific indications are: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) pseudoarthrosis, (3) spondylolysis, (4) spinal deformation such as kyphosis and lordosis, (5) fracture, (6) unsuccessful previous attempts at spinal surgery, (7) tumor resection, (8) correction of severe instability and/or deformity when used in addition to a posterior spinal instrumentation system, (9) neoplastic disease, and/or (10) deformity associated with deficient posterior elements, such as laminectomy, spina bifida, or myelomeningocele.

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

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Milhorn

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

510(k) Number K031533 000032