AUG 2 3 2005

K052180

VERTEX® Reconstruction System
510(k) Summary
July 2005

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

Contact: Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs

II. **Product Name:** VERTEX Reconstruction System

Classification Name: Spinal Interlaminal Fixation Orthosis

Regulation Number: 888.3050

Code: KWP

III. Description:

The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of rods, hooks, screws, multi-axial 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.

The VERTEX® Reconstruction System is fabricated from medical grade titanium or titanium alloy. The VERTEX® Reconstruction System also includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium or titanium alloy implants only. **Do not use with stainless steel.**

The purpose of this submission was to add modified setscrews to the existing system.

IV Indications

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the VERTEX® Reconstruction 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.

K052180

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 (3.5mm, 4.0mm and 4.5mm cancellous and 4.0mm cortical) is limited to placement in T1-T3 in treating thoracic conditions only. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS™ Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

V. Substantial Equivalence:

Documentation, including mechanical test results, has been provided which demonstrates that the subject VERTEX™ Reconstruction System components are substantially equivalent to VERTEX® Reconstruction System components previously cleared in K042498 (SE 10/07/04) and K042789 (SE 12/21/04).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K052180
Trade/Device Name: VERTEX® Reconstruction System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: August 9, 2005
Received: August 10, 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.

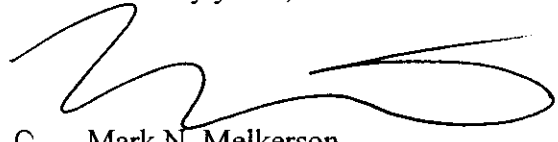
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

510(k) Number (if known): K052180

Device Name: VERTEX® Reconstruction System

Indications for Use

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the VERTEX® Reconstruction 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.

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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.

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

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 K052180