VERTE-STACK® Spinal System
510(k) Summary
January 2007

I. **Company:** **Medtronic Sofamor Danek USA, Inc.**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
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MAR 14 2007

Contact: **Christine Scifert, M.S., M.E.M.**
Group Director, Regulatory Affairs

II. **Proprietary Trade Name: VERTE-STACK® Spinal System**

III. **Classification Name/Product Code: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)**

IV. **Product Code: MQP**

V. **Product Description**

The VERTE-STACK® device consists of hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK® device consists of three components (one hollow center cage, and two hollow add-on cages). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System implant components are made of medical grade PEEK-OPTIMA LT1 along with a marker made from either Tantalum or titanium. Alternatively, VERTE-STACK® Spinal System may be manufactured from titanium alloy.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured from PEEK may be used with stainless steel or titanium supplemental

fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission was to modify the geometry of the implants and to include additional sizes into the existing VERTE-STACK® Spinal System.

V. Indications

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation, including mechanical test results, was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System (K052931, SE 11/13/2005; and K062133, SE 09/26/2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert, M.S., M.E.M.
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, TN 38132

MAR 14 2007

Re: K070173
Trade/Device Name: VERTE-STACK® Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 22, 2007
Received: February 26, 2007

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) 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

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

Enclosure

January 2007

510(k) Number (if known): K070173

Device Name: VERTE-STACK® Spinal System

Indications for Use:

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

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 K070173