

**CD HORIZON® Spinal System**  
**Summary of Safety and Effectiveness**  
**June 2003**

- I. Company: Medtronic Sofamor Danek, Inc. USA**  
**1800 Pyramid Place**  
**Memphis, TN 38132**  
**(901) 396-3133**
- II. Proposed Proprietary Trade Name: CD HORIZON® Spinal System**
- III. Classification Name: Spinal Interlaminar Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw Spinal System (per 21 CFR Section 888.3050, 888.3060 and/or 888.3070)**
- IV. Product Description**

The CD HORIZON® Spinal System consists of a variety of rods, hooks, screws, CROSSLINK® plates, staples, and other connecting components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The CD HORIZON® Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. If necessary, the CD HORIZON® Spinal System can be connected to the VERTEX™ Reconstruction System through a rod connector.

Certain implant components from other Medtronic Sofamor Danek spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers; GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS® bolts; and Medtronic Sofamor Danek Multi-Axial rods and screws.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE® rods and screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

## V. Indications

The CD HORIZON® system is intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (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) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

### **SEXTANT Instrumentation**

When used in a percutaneous posterior approach with the SEXTANT instrumentation, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for the following indications:

When used as a pedicle screw fixation system the CD HORIZON® Cannulated M8 Multi-Axial Screw components are indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a posterior spine thoracic/lumbar system, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for: (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) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. degenerative scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

#### **CD HORIZON® ECLIPSE®**

The CD HORIZON® ECLIPSE® components are intended for the following indications: When used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System is intended for the following indications: (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) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

#### **CD HORIZON® Spinal System connected to VERTEX™ Reconstruction System**

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. When connecting to the VERTEX™ Reconstruction System in the cervical spine, components are intended for the following 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.

#### **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.

#### **Multi-axial Screws/Lateral Connectors**

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

Titanium ATLAS™ Cable and the CD HORIZON® Spinal System may be used with the VERTEX™ Reconstruction System.

#### **VI. Substantial Equivalence**

Documentation was provided which demonstrated the CD HORIZON® SPINOUS PROCESS Plate to be substantially equivalent to pre-amendment devices, as well as to the previously cleared CD HORIZON® Spinal System.



SEP - 3 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K031833  
Trade Name: CD HORIZON® Spinal System – Addition of Screw w/ Dual Rod Channel  
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050  
Regulation Name: Pedicle screw spinal system, Spinal intervertebral body fixation  
orthosis, Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: MNI, MNH, KWQ, KWP  
Dated: July 31, 2003  
Received: August 4, 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.

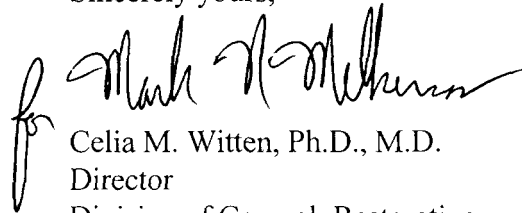
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Richard W. Treharne, Ph.D.

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K031833

Device Name: CD HORIZON® Spinal System – Addition of Screw w/ Dual Rod Channel

**Indications for Use:**

The CD HORIZON® system is intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (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) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

*for Mark A. Miller*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices  
510(k) Number K031833  
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**SEXTANT Instrumentation**

When used in a percutaneous posterior approach with the SEXTANT instrumentation, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for the following indications:

When used as a pedicle screw fixation system the CD HORIZON® Cannulated M8 Multi-Axial Screw components are indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a posterior spine thoracic/lumbar system, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for: (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) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. degenerative scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

**CD HORIZON® ECLIPSE®**

The CD HORIZON® ECLIPSE® components are intended for the following indications:

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**CD HORIZON® Spinal System connected to VERTEX™ Reconstruction System**

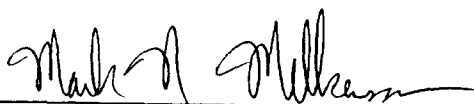
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**Hooks and Rods**

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.

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

(Continued on the next page)

510(k) Number K031833  
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**Multi-axial Screws/Lateral Connectors**

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Titanium ATLAS™ Cable and the CD HORIZON® Spinal System may be used with the VERTEX™ Reconstruction System.

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

\_\_\_\_\_ Concurrence of CDRH, Office of Evaluation (ODE) \_\_\_\_\_

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-counter Use \_\_\_\_\_

(Optional 1-2-96)

for Mark A. Mellan  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K031833

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