K123246

NOV 16 2012

510(k) Summary

MEDTRONIC Sofamor Danek

CD HORIZON SPIRE™ Z SPINAL SYSTEM

October 16, 2012

I.	**Company:**	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 (901) 396-3133
II.	**Contact:**	Julie Bassett Principal Regulatory Affairs Specialist Telephone: (901) 399-3248 Fax: (901) 346-9738
III.	**Proprietary Trade Name:**	CD HORIZON SPIRE™ Z Spinal System
IV.	**Classification Names:**	Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Fixation Orthosis, and/or Pedicle Screw Spinal System (21 CFR 888.3050, 21 CFR 888.3060, and 21 CFR 888.3070)
	Class:	III (Pre-Amendment)
	Product Code:	KWP, KWQ, MNH, MNI, NKB, NQP, and OSH

V. Description:

The CD HORIZON SPIRE™ Z Spinal System (subject device) is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. The CD HORIZON SPIRE™ Z Spinal System is a subset of the CD HORIZON® Spinal System.

VI. Indications for Use:

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON®

Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

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. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

VII. Summary of the Technological Characteristics:

The CD HORIZON SPIRE™ Z Spinal System has the same fundamental technology as the predicate CD HORIZON SPIRE™ Z Spinal System. The only changes have been to add a new inserter/compressor instrument to help facilitate the implantation of the CD HORIZON SPIRE™ Z plate assemblies and update the packaging for the convenience of our customers. In addition, traceability tags are being added to the plate assemblies to enable the surgeon to scan the information into the patient's electronic health record and for ease of tracking in the event of a recall.

VIII. Identification of Legally Marketed Devices:

The subject device has the same intended use and fundamental scientific technology as the predicate CD HORIZON SPIRE™ Z Spinal System (K092325, SE 12/15/2009). The subject device has the same indications for use as the most recently cleared CD HORIZON® Spinal System (K122433, SE 9/28/2012).

IX. Discussion of Non-Clinical Testing:

A new Inserter/Compressor instrument was added to the CD HORIZON SPIRE™ Z Spinal System. The subject and predicate CD HORIZON SPIRE™ Z Spinal System devices are identical in terms of indications for use, intended use, performance specifications, and technological characteristics. Assessment of the modifications has been completed in accordance with internal Medtronic procedures. Cleaning and sterilization assessments have also been conducted to ensure that the implants and instruments in the CD HORIZON SPIRE™ Z Spinal System can be adequately cleaned and sterilized using the cleaning, and sterilization instructions provided in the Instructions for Use.

In addition, ship testing was performed according to ASTM 4169-09 on the new packaging configuration to ensure that the CD HORIZON SPIRE™ Z Spinal System would not be damaged during shipping.

XI. Conclusion:

Based on the risk analysis and additional supporting documentation provided in this pre-market notification, Medtronic believes that the subject CD HORIZON SPIRE™ Z Spinal System is substantially equivalent to the predicate, CD HORIZON SPIRE™ Z Spinal System (K092325, SE 12/15/2009).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Julie Bassett
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K123246
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, KWQ, MNH, MNI, NQP
Dated: October 16, 2012
Received: October 17, 2012

Dear Ms. Bassett:

This letter corrects our substantially equivalent letter of November 16, 2012.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123246

Device Name: CD Horizon® Spinal System

Indications for Use:

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

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. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

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)

Ronald P. Jean

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123246