DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 4, 2017

Medtronic Sofamor Danek USA
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K170347
Trade/Device Name: CD HORIZON™ Fenestrated Screw Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: January 31, 2017
Received: February 3, 2017

Dear Mr. Grant:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170347

Device Name

CD HORIZON Fenestrated Screw Set

Indications for Use *(Describe)*

When used without cement, the CD HORIZON Fenestrated Screws (with or without SEXTANT® or LONGITUDE® instrumentation) are 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), pseudarthrosis, and/or failed previous fusion.

When used in conjunction with KYPHON HV-R™ Fenestrated Screw Bone Cement, the CD HORIZON™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD HORIZON™ Fenestrated Screws augmented with KYPHON HV-R™ Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Medtronic Sofamor Danek USA
CD HORIZON™ Fenestrated Screw Set
March 2017

Submitter	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact(s)	Lee Grant Distinguished Regulatory Affairs Advisor Direct Telephone – 901-344-0807
Date Prepared	March 30, 2017
Common Name	CD HORIZON™ Fenestrated Screw Set
Regulatory Class **Regulation Number** **Regulation Name and Device Product Classification Code**	CD HORIZON™ Fenestrated Screw Set Class II, NKB 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System
Predicate Devices	K113174 - CD HORIZON™ Spinal System (SE 11/21/11) **Secondary Predicate** K152604 – CD HORIZON™ Fenestrated Screw Set (SE 01/06/16) The predicate devices have not been subject to a design related recall
Description of Device	The CD HORIZON™ Fenestrated Screw Set consists of a variety of cannulated multi-axial screws (MAS) with fenestrations offered in diameters ranging from 4.5mm to 10.5mm, with lengths ranging from 30-100mm based on CD HORIZON™ LEGACY™ and CD HORIZON™ SOLERA™ implants contained in the CD HORIZON™ Spinal System. The CD HORIZON™ Fenestrated Screws are specifically designed to connect to 4.75mm, 5.5mm, and 6.0mm diameter rods and associated connecting components contained within the CD HORIZON™ Spinal System. The screws contain six fenestrations near the distal tip of the screw which provides a controlled means to deliver a small amount of polymethylmethacrylate (PMMA) bone cement into a targeted vertebral body. These implants may also serve as traditional pedicle screws when used without bone cement. These screws are provided non-sterile.
Submission Purpose	The subject CD HORIZON™ Fenestrated Screws are being introduced into the market for use without cement, for standard CD HORIZON® Spinal System indications.
Indications for Use:	When used without cement, the CD HORIZON Fenestrated Screws (with or without SEXTANT® or LONGITUDE® instrumentation) are 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), pseudarthrosis, and/or failed previous fusion. When used in conjunction with KYPHON HV-R™ Fenestrated Screw Bone Cement, the CD HORIZON™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time

	period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD HORIZON™ Fenestrated Screws augmented with KYPHON HV-R™ Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.
Comparison of Technological Characteristics with the Predicate Devices	The screws which comprise the CD HORIZON™ Fenestrated Screw Set are identical to those cleared in the previous CD HORIZON™ Fenestrated Screw Set in K152604 for the same indications when used in conjunction with cement augmentation. These screws were declared substantially equivalent to non-augmented CD HORIZON Spinal System screws cleared in K113164 for which the same non-cement augmented indications stated in the Indications for Use section. No modifications have been made to the subject screws. They are identical to the predicate screws with respect to indications, design, size, intended use, cannulation, fundamental scientific technology, and materials.
Performance Data	Non-Clinical mechanical testing of the subject fenestrated screws demonstrating substantial equivalence to the traditional pedicle screws found in the predicate CD HORIZON® Spinal System was previously provided in K152604.
Conclusion	Based on the information provided herein, the subject CD HORIZON® Fenestrated Screws are substantially equivalent to the predicate CD HORIZON® Spinal System screws cleared in K113174.