



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

Medtronic Sofamor Danek USA, Incorporated
Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

February 18, 2016

Re: K153442

Trade/Device Name: CD HORIZON® Spinal System, Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION® System, Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System, Medtronic Navigated Reusable Instruments for Use with the STEALTHSTATION® and IPC® POWEREASE™ Systems

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class III

Product Code: NKB, OSH, MNH, MNI, KWQ, KWP, OLO, HWE

Dated: November 25, 2015

Received: November 27, 2015

Dear Ms. Joe:

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 Parts 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 yours,

Mark N. Melkerson -S

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)

K153442

Device Name

CD HORIZON® Spinal System

Indications for Use (Describe)

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 progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. 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.

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)

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Indications for Use

510(k) Number (if known)

K153442

Device Name

MEDTRONIC NAVIGATED MANUAL REUSABLE INSTRUMENTS FOR USE WITH THE STEALTHSTATION® SYSTEM

Indications for Use (Describe)

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy during spinal surgery. The Navigated Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery.

The Navigated Probe is intended to be used during pedicle and disc preparation during spinal fusion procedures.

Navigated instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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Indications for Use

510(k) Number (if known)

K153442

Device Name

MEDTRONIC REUSABLE INSTRUMENTS FOR USE WITH THE IPC® POWEREASE® SYSTEM

Indications for Use (Describe)

IPC® System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC® POWEREASE® System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

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)

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Indications for Use

510(k) Number (if known)

K153442

Device Name

MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS FOR USE WITH STEALTHSTATION® AND IPC®
POWEREASE™ SYSTEMS

Indications for Use (Describe)

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

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)

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510(k) SUMMARY**February 2016**

I.	Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 (901)396-3133
	Contact	Lila Joe Principal Regulatory Affairs Specialist
	Date Prepared	February 16, 2016
II.	Device	
	Name of Device	CD HORIZON® Spinal System, Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION® System, Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System, Medtronic Navigated Reusable Instruments for Use with the STEALTHSTATION® and IPC® POWEREASE™ Systems
	Classification Name	Pedicle Screw Spinal System - NKB, OSH, MNI, MNH, KWQ, KWP (For Bone Screws) Stereotaxic Instrument - OLO (For Navigated Instruments) Surgical Instrument Motors and Accessories/Attachments - -HWE (For Instruments Compatible with the IPC® POWEREASE® System)
	Classification	Class III Pre-Amendment (Screws) Class II (Instruments)
	Product Codes	NKB, OSH, MNH, MNI, KWP, KWQ (Bone Screws) 21 CFR 888.3070 21 CFR 888.3060 21 CFR 888.3050 OLO (Navigated Instruments) 21 CFR 882.4560

HWE (IPC® POWEREASE® Compatible Instruments)
21 CFR 878.4820

Predicates

There are 9 Predicates.

CD HORIZON® Spinal System

K113174, S.E. 11/21/2011 (Primary Predicate)

K050439, S.E. 03/24/2005

K102555, S.E. 11/17/2010

K152457, S.E. 10/27/2015

DePuy Spine Inc. - VIPER

K121020, S.E. 05/03/2012

Medtronic Navigated Instruments

K150231, S.E. 06/16/2015

IPC® POWEREASE® System

K111520, S.E. 10/26/2011

Medtronic Navigated Taps and Screwdrivers

K124004, S.E. 03/22/2013

K140454, S.E. 05/22/2014

The predicates have not been subject to a design related recall.

III. Product Description

CD HORIZON® Spinal System

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The subject CD HORIZON® Spinal System offers cannulated, multi-axial bone screws that have an opened head (MAS) or closed head (CMAS). The subject screws offer additional angulation for anatomies or trajectories that require a sharper angle than what is typically used when placing a rod into the screw head. The subject MAS and CMAS are provided both sterile and non-sterile.

Medtronic Reusable Instruments Only Compatible with the STEALTHSTATION® System

The subject Medtronic Navigated Reusable probe is specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. The subject probe is used to prepare for placement of the subject bone screws into the bone.

Medtronic Reusable Instruments Only Compatible with the IPC® POWEREASE® System

The subject Medtronic Reusable drivers, torque multiplier adapter, and taps are spine preparation instruments made of high grade stainless steel. The subject drivers, torque multiplier adapter, and taps are compatible with Medtronic's IPC® POWEREASE® System may be connected to the IPC® POWEREASE® handpiece. The subject drivers, and taps can be used manually using existing Medtronic Class I Exempt quick connect handles in place of the IPC® POWEREASE® handpiece.

Medtronic Reusable Instruments Compatible with the STEALTHSTATION® System and IPC® POWEREASE® Systems

The subject Medtronic Navigated Reusable drivers and taps are spine preparation instruments made of high grade stainless steel. These instruments were specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. The subject drivers and taps are also compatible with Medtronic's IPC® POWEREASE™ System when connected to the POWEREASE™ handpiece or may be used manually with existing Medtronic Class I Exempt quick connect handles in place of the IPC® POWEREASE® handpiece or the NavLock™ tracker.

IV. Indications for Use:

CD HORIZON® Spinal System

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 progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. 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.

Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION® System

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy during spinal surgery. The Navigated Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery.

The Navigated Probe is intended to be used during pedicle and disc preparation during spinal fusion procedures.

Navigated instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System

IPC® System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC® POWEREASE® System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

Medtronic Navigated Reusable Instruments for Use with STEALTHSTATION® System and IPC® POWEREASE™ Systems

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

V. Comparison of Technological Characteristics

CD HORIZON® Spinal System

The primary predicate for the CD HORIZON® Spinal System is the predicate CD HORIZON® Spinal System (K113174, S.E. 11/21/2011).

The subject CD HORIZON® Spinal System bone screws have the same or similar indications, intended use, and similar materials as the following FDA cleared predicates K113174, S.E. 11/21/2011, K050439 (S.E. 03/24/2005), K102555 (S.E. 11/17/2010), and K121020 (S.E. 05/03/2012). The predicate and subject screws have the same function. However, the predicate bone screws do differ in the scientific fundamental technology.

The main difference in the design of the predicate and subject screws is in the degree of angulation provided by the predicate and subject bone screws. The predicate bone screws are assembled using a metal ring compared to a metal wire to assemble the subject bone screws and allow angulation for anatomies or trajectories that require a sharper angle than what is typically used when placing a rod into the screw head.

Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION® System

The subject navigated probe is identical in intended use and material as the navigated probes cleared in K124004 (S.E. 03/22/2013). The difference between the subject and navigated probe is that the subject probe is designed so that the tip dimension is the same as the minor diameter of the smallest subject tap.

Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System

The subject standard driver and standard taps are identical in intended use and material as their predicates in K111520 (S.E. 10/26/2011). The difference between the subject and predicate driver and taps is that the subject driver and taps are designed to interface with the subject bone screws. The subject torque multiplier adapter is identical in material as its predicate cleared in K111520 (S.E. 10/26/2011). The subject torque multiplier is similar to the intended use of its predicate cleared in K111520 (S.E. 10/26/2011), which is to provide increased torque limit of the handpiece. The torque of the predicate adapter is used to break off set screw caps, while the subject adapter is used to place screws.

Medtronic Navigated Reusable Instruments for Use with STEALTHSTATION® System and IPC® POWEREASE™ Systems

The subject navigated taps and drivers that are compatible with the STEALTHSTATION® System and IPC® POWEREASE™ Systems are identical to their predicates (K124004, S.E. 03/22/2013 and K140454, S.E. 05/22/2014) in intended use and materials. The difference between the subject and predicate taps and drivers is that they are designed to interface with the subject bone screws.

VI. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the subject CD HORIZON® BALLAST™ Spinal System bone screws was conducted in accordance with the FDA's Draft Guidance for Industry and FDA Staff, *Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

The subject bone screws are manufactured from

- *ASTM F1537, Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*
- *ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications*
- *ASTM F67, Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*

The bone screws are permanent implants and will be classified as "Implant Devices - Tissue/bone - C Permanent (>30 days)" according to FDA's Draft Guidance for Industry and FDA Staff, *Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

Cobalt chrome, titanium alloy, and commercially pure titanium have a long history of safe and effective use in predicate spinal implants. Therefore, no new biocompatibility testing is required.

The subject probe, torque multiplier adapter, taps, and drivers, are manufactured from:

- Stainless Steel (Direct Patient Contact)
- Radel End Caps (Indirect Patient Contact)
- Silicone Handle (Indirect Patient Contact)

- Titanium Alloy (per ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Application - Indirect Patient Contact)
- Polyetheretherketone - PEEK (Indirect Patient Contact)

The subject instruments are classified as limited, up to 24 hours of body contact according to FDA's Draft Guidance for Industry and FDA Staff: *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

The radel end caps and silicone handles have indirect patient contact, therefore, no new biocompatibility testing is required according to FDA's Draft Guidance for Industry and FDA Staff: *Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

Medical grade stainless steel, titanium alloy, and PEEK have a long history of safe and effective use in spinal surgery. Therefore, no new biocompatibility testing is required.

Mechanical Testing

In accordance with the *Guidance for Industry and FDA Staff - Spinal System 510(k)'s*, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Design verification testing for the subject bone screws was completed in accordance with

- *ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model,*
- *ASTM F1798, Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies in Spinal Arthrodesis Implants*

The tests completed were:

- Static Compression
- Static Torsion
- Construct Compression Fatigue

- Axial Grip
- Axial Torsion
- Flexion Extension Static
- Flexion Extension Fatigue

The subject devices met the pre-determined acceptance criteria for all tests. Therefore, design verification testing determined that the subject bone screws are substantially equivalent to the predicate Medtronic bone screws.

Design validation testing was performed that demonstrated that the subject instruments performed as intended.

VII. Conclusions

Based on the test results and additional supporting information provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.