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

May 11, 2017

Medtronic Sofamor Danek
Ms. Kanesha Hines
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K170679
Trade/Device Name: CD HORIZON® Spinal 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: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, OLO, HWE
Dated: March 3, 2017
Received: March 6, 2017

Dear Ms. Hines:

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)*
K170679

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K170679

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K170679

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

MEDTRONIC
CD HORIZON® Spinal System

Submitter:	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Kanesha Hines Regulatory Affairs Specialist Direct Telephone: (901)399-2670
Date Prepared	May 4, 2017
Name of Device	CD HORIZON® Spinal System, Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System, Medtronic Navigated Reusable Instruments for Use with the STEALTHSTATION® and IPC® POWEREASE™ Systems
Common Name	Bone Screws, Pedicle Screws, Taps, Drivers, Tab Extenders, Extender Cap, and Accessories
Classification Name	CD HORIZON® Spinal System Thoracolumbosacral Pedicle Screw System - NKB, KWQ, KWP Medtronic Navigated Taps and Screwdrivers Stereotaxic Instrument - OLO IPC® POWEREASE® System Surgical Instrument Motors and Accessories/Attachments - HWE
Classification	Class II (Implants) Class II (Instruments/Accessories)
Product Codes	NKB, 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

Predicate Devices	There are 11 Predicates. CD HORIZON® Spinal System Primary Predicate 1- K113174 CD HORIZON® SOLERA® Ø5.5/6.0mm (S.E. 11/21/2011) **Predicate 2**- K141494 CD HORIZON® SOLERA® Ø4.75 ATS (S.E. 08/06/2014) **Predicate 3**- K143375 CD HORIZON® SOLERA® VOYAGER™ 4.75 Spinal System (S.E. 02/13/2015) **Predicate 4**- K132639 CD HORIZON® Prebent Rods and Rod Inserter (S.E. 11/25/2013) **Predicate 5**- K121680 CD HORIZON® SOLERA® Additional Rods (S.E. 07/05/2012) **Predicate 6**- K122862 CD HORIZON® Longitude II and Additional Rods (S.E. 10/03/2012 **Predicate 7**- K113529 CD HORIZON® VOYAGER™ 5.5 Spinal System (S.E. 02/09/2012) IPC® POWEREASE® System **Predicate 8**- K153463 CD HORIZON® Taps Compatible with IPC® POWEREASE® System (S.E. 12/30/2015) **Predicate 9**- K111520 CD HORIZON® Reusable Instruments Compatible with IPC® POWEREASE® System (S.E. 10/26/2011) Medtronic Navigated Taps and Screwdrivers **Predicate 10**- K140454 Navigated CD HORIZON® SOLERA® Screwdriver/Taps (S.E. 05/22/2014) **Predicate 11**- K124004 Medtronic Navigated Taps and Screwdrivers (S.E. 03/22/2013) *The predicates have not been subject to a design related recall.*
Description of Devices	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 devices in this submission include:

	Additions to the existing CD HORIZON® SOLERA® Ø5.5/6.0 Spinal System • Ø5.5/6.0 Awl Tap Screws (ATS) • Ø5.5 Capped Rods • Ø5.5 Percutaneous Rods Additions to the existing CD HORIZON® SOLERA® VOYAGER™ Ø4.75 Spinal System • Ø4.75 Awl Tap Screws (ATS) Creating the new CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Spinal System • Cannulated Multi-Axial Screws (MAS) • Awl Tap Screws (ATS) • Capped Rods • Percutaneous Rods • Tab Extenders • Extender Cap • Taps and Driver compatible with IPC® POWEREASE® System • Navigated Driver compatible with STEALTHSTATION® and IPC® POWEREASE® Systems • System specific cases and trays <u>Medtronic Reusable Instruments Only Compatible with the IPC® POWEREASE® System</u> The subject Medtronic Reusable taps and driver are spine preparation instruments made of high grade stainless steel. The subject taps and driver are compatible with Medtronic's IPC® POWEREASE® System and may be connected to the IPC® POWEREASE® handpiece. The subject taps and driver can be used manually using existing Medtronic Class I Exempt quick connect handles in place of the IPC® POWEREASE® handpiece. <u>Medtronic Reusable Instruments Compatible with the STEALTHSTATION® System and IPC® POWEREASE® Systems</u> The subject Medtronic Navigated Reusable driver is a spine preparation instrument made of high grade stainless steel. This instrument was specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. The subject driver is 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.
Indications for Use	<u>CD HORIZON® Spinal System</u> The subject devices have identical indications to the most recently cleared CD HORIZON® Spinal System indications in K162379 (S.E. 11/16/2016) *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 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 Reusable Instruments Compatible with the IPC® POWEREASE® System The subject devices have identical indications to the those cleared in K143019 (S.E. 04/08/2015) *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 Reusable Instruments Compatible with the STEALTHSTATION® System and IPC® POWEREASE® System The subject devices have identical indications to those cleared in K140454 (S.E. S.E. 05/22/2014). *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.*
Comparison of Technological Characteristics with the Predicate Devices	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 devices have the same or similar indications, intended use, and similar materials as the following FDA cleared Primary Predicate 1 K113174, (S.E. 11/21/2011), Predicate 2 K141494 (S.E. 11/21/2011), Predicate 3 K143375 (S.E. 02/13/2015), Predicate 4

	K132639 (S.E. 11/25/2013), Predicate 5 K121680 (S.E. 07/05/2012), Predicate 6 K122862 (S.E. 10/03/2012), and Predicate 7 K113529 (S.E. 02/09/2012). The predicate and subject devices have the identical function and scientific fundamental technology. Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System The subject taps and driver are identical in intended use and material as their predicates in Predicate 8 K153463 (S.E. 12/30/2015) and Predicate 9 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. Medtronic Navigated Reusable Instruments for Use with STEALTHSTATION® System and IPC® POWEREASE™ Systems The subject navigated driver that is compatible with the STEALTHSTATION® System and IPC® POWEREASE™ Systems is identical to its predicate (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 driver is that it is designed to interface with the subject bone screws.
Performance Data	The following performance data were provided in support of substantial equivalence. **Validation Testing** To support the expanded intended use for the Predicate 2 (K141494, S.E. 08/06/2014) CD HORIZON® SOLERA® Ø4.75 ATS, subject CD HORIZON® SOLERA® Ø5.5/6.0 ATS, CD HORIZON® SOLERA® VOYAGER® Ø4.75 and CD HORIZON® SOLERA® VOYAGER® Ø5.5/6.0 ATS, a pre-clinical confirmatory validation activity was conducted in cadaver models which demonstrated that the proposed ATS devices could be used for percutaneous use. For the remainder of the subject devices, Medtronic believes that the existing validation activities performed for the predicate devices are sufficient for establishing substantial equivalence. **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. Medtronic believes that testing is not warranted for the subject implants, subject instruments compatible with IPC® POWEREASE® System and subject Tab Extenders and Extender Cap as they do not present a new worst case when compared to the predicate devices. For the subject instruments compatible with STEALTHSTATION® System and IPC® POWEREASE™ Systems, software verification testing and activities were performed that demonstrated that the subject instruments performed as intended.
Conclusion	Based on the test results and additional supporting information provided in this premarket notification, Medtronic believes the subject devices are at least as safe as and effective as the legally marketed predicate devices: • Primary Predicate 1- K113174 CD HORIZON® SOLERA® Ø5.5/6.0mm (S.E. 11/21/2011) • Predicate 2- K141494 CD HORIZON® SOLERA® Ø4.75 ATS (S.E. 08/06/2014) • Predicate 3- K143375 CD HORIZON® SOLERA® VOYAGER™ 4.75 Spinal System (S.E. 02/13/2015) • Predicate 4- K132639 CD HORIZON® Prebent Rods and Rod Inserter (S.E. 11/25/2013) • Predicate 5- K121680 CD HORIZON® SOLERA® Additional Rods (S.E. 07/05/2012) • Predicate 6- K122862 CD HORIZON® Longitude II and Additional Rods (S.E. 10/03/2012 • Predicate 7- K113529 CD HORIZON® VOYAGER™ 5.5 Spinal System (S.E. 02/09/2012) • Predicate 8- K153463 CD HORIZON® Taps Compatible with IPC® POWEREASE® System (S.E. 12/30/2015) • Predicate 9- K111520 CD HORIZON® Reusable Instruments Compatible with IPC® POWEREASE® System (S.E. 10/26/2011)

	• Predicate 10- K140454 Navigated CD HORIZON® SOLERA® Screwdriver/Taps (S.E. 05/22/2014) • Predicate 11-K124004 Medtronic Navigated Taps and Screwdrivers (S.E. 03/22/2013)