Medtronic Sofamor Danek USA, Inc
Mr. Ankit Shah
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K180851
Trade/Device Name: VERTEX™ Reconstruction System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 29, 2018
Received: April 2, 2018

Dear Mr. Shah:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S
for MNM

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180851

Device Name
VERTEX™ Reconstruction System

Indications for Use *(Describe)*

The VERTEX™ Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VERTEX™ Reconstruction System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the VERTEX™ Reconstruction System may be connected to the CD HORIZON™ Spinal System rods with the VERTEX™ rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX™ Reconstruction System to the CD HORIZON™ Spinal System. Refer to the CD HORIZON™ Spinal System package insert for a list of the CD HORIZON™ Spinal System 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.

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510(k) Summary

March 2018

I. Company: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133

Contact: Ankit K. Shah
Sr. Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: ankit.k.shah@medtronic.com

Date: 29 March 2018

II. Proprietary Trade Name: VERTEX™ Reconstruction System
Classification Name: Orthosis, Cervical Pedicle Screw Spinal Fixation (Unclassified)
Classification: Pre-Amendment
Product Code: NKG
Classification Name: Appliance, Fixation, Spinal Interlaminal (21 CFR§ 888.3050)
Classification: Class II
Product Code: KWP

III. Predicate Device:

Primary Predicate

- K152338 VERTEX™ Reconstruction System (S.E.10/28/2015)

Additional Predicates

- K123656 VERTEX™ Reconstruction System (S.E.02/25/2013)
- K003780 VERTEX™ Reconstruction System (S.E. 09/28/2001)
- K052402 VERTEX™ Reconstruction System (S.E. 09/23/2005)
- K070742 VERTEX™ Reconstruction System (S.E. 09/14/2007)
- K080805 VERTEX™ Reconstruction System (S.E. 04/18/2008)
- K163375 INFINITY™ OCT System (S.E. 08/21/2017)

These predicates have not been subject to a design-related recall. No reference devices were used in this submission.

IV. Device Description:

The VERTEX™ Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations. Conditions of the cervical spine, such as degenerative disease, tumor, or trauma, can lead to instability and pain for patients. In order to treat the instability, surgeons may need to use implants to reconstruct the spine. The VERTEX™ Reconstruction System is a comprehensive set of options that provides adjustability, flexibility, and adaptability to meet the anatomical challenges of the occipitocervical and upper thoracic spine. The VERTEX™ Reconstruction System is intended to be implanted by an orthopedic surgeon as described in the Surgical Technique. Each construct is specifically designed for each individual case. The components of the VERTEX™ Reconstruction System are fabricated from medical grades of commercially pure titanium, titanium alloy, and cobalt chromium. The VERTEX™ Reconstruction System also includes a retaining ring for the use with the multi-axial screw which is fabricated from Shape Memory Alloy, Nitinol-NiTi.

V. Indications for Use:

The VERTEX™ Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VERTEX™ Reconstruction System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the VERTEX™ Reconstruction System may be connected to the CD HORIZON™ Spinal System rods with the VERTEX™ rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX™ Reconstruction System to the CD HORIZON™ Spinal System. Refer to the CD HORIZON™ Spinal System package insert for a list of the CD HORIZON™ Spinal System indications of use.

VI. Summary of the Technological Characteristics:

The subject rods have identical indications, intended use, fundamental scientific technology, materials, dimensions and design features as the VERTEX™ Reconstruction System predicates previously cleared by FDA in; K152338 (S.E. 10/28/2015), K123656 (S.E. 02/25/2013), K003780 (S.E. 09/28/2001), K052402 (S.E. 09/23/2005), K070742 (S.E. 09/14/2007), K080805 (S.E. 04/18/2008). Like the predicate rods, the subject rods are available in titanium alloy and cobalt chromium alloy. The only technological difference between the subject and predicate VERTEX™ Reconstruction System devices is as below: The subject VERTEX™ rods are provided sterile while the predicate VERTEX™ rods are provided non-sterile. The sterilization method used for subject rods, is identical to recently cleared rods within the Infinity OCT System K163375 (S.E. 08/21/2017).

VII. Performance Data:

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject VERTEX™ Reconstruction System implants are permanent implants (> 30 days) and will be classified as body contacting devices 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". The subject implants and instruments are manufactured from identical materials as the predicate devices, in accordance with the following standards:

- ASTM F136: Standard Specification for Wrought Ti-6Al-4V ELI Alloy for Surgical Implant
- ASTM F1537: Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants

The materials used for manufacturing the subject device have a long history of safe and effective use in predicate spinal implants, and biocompatibility testing is not required.

Mechanical Testing

Non-clinical mechanical testing was not performed on the sterile implants. The subject implants are the same as the predicate devices in terms of material, diameter, sizes and intended use. The predicate rods were tested in accordance to ASTM F1717. The subject devices do not introduce a new worst case, hence testing conducted on predicate rods is sufficient for subject rods. Medtronic believes that the subject implants do not introduce a new worst case scenario and are substantially equivalent to the predicate device.

Non-Pyrogenicity Endotoxin Testing

The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case subject implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

VIII. Conclusions:

Based on the sterilization assessment, packaging assessment, and additional supporting documentation provided in this pre-market notification, the subject VERTEX™ Reconstruction System implants demonstrate substantial equivalence to the previously listed predicate devices.