



Food and Drug Administration
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Medtronic Sofamor Danek USA, Incorporated
Ms. Victoria Scheitlin
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

October 28, 2015

Re: K152338
Trade/Device Name: VERTEX[®] Reconstruction System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: August 18, 2015
Received: August 19, 2015

Dear Ms. Scheitlin:

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)

K152338

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.

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510(k) SUMMARY
MEDTRONIC Sofamor Danek
MRI Update for VERTEX® Reconstruction System
October 2015

- I. Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(800) 876-3133
Contact: Victoria Scheitlin
Regulatory Affairs Specialist
Telephone: (901) 344-0706
Fax: (901) 346-9738
Date Prepared: October 22, 2015
- II. Device:**
Name of Device: VERTEX® Reconstruction System
Classification Name: Orthosis, Cervical Pedicle Screw Spinal Fixation (Unclassified)
Class: Pre-Amendment
Product Code: NKG
Classification Name: Appliance, Fixation, Spinal (21 CFR§ 888.3050)
Class: II
Product Code: KWP
- III. Predicate Devices:** Primary Predicate – VERTEX® Reconstruction System K143471 (S.E. 02/06/2015)
- Reference Device – VERTEX® Reconstruction System K003780 (S.E. 09/28/2001)
 - Reference Device – VERTEX® Reconstruction System K022015 (S.E. 07/18/2002)
 - Reference Device – VERTEX® Reconstruction System K042498 (S.E. 10/07/2004)
 - Reference Device – VERTEX® Reconstruction System K052402 (S.E. 09/23/2005)
 - Reference Device – VERTEX® Reconstruction System K052376 (S.E. 01/05/2006)
 - Reference Device – VERTEX® Reconstruction System K071942 (S.E. 12/11/2007)
 - Reference Device – VERTEX® Reconstruction System K123906 (S.E. 04/01/2013)
- The predicate has not been subject to a design related recall. Seven reference devices were used in this submission.*

IV. 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 disc 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 (ASTM F67-13), titanium alloy (ASTM F136-13), and cobalt chromium (ASTM F1537-11). 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 (ASTM F2063-12).

The sole purpose for this submission is to update the labeling for the VERTEX® Reconstruction System to include MRI safety information while also providing MRI technologists with a method of concluding whether an MRI scan can be performed and specific instructions on how to perform the scan.

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. Comparison of Technological Characteristics with the Predicate Devices:

The design/specifications of the subject device are not being addressed. No changes have occurred for the device and the subject device is considered substantially equivalent to the previously cleared 510(k) submission:

1. The following submission contains identical indications for use as the subject device:
 - i. Primary Predicate – VERTEX® Reconstruction System K143471 (S.E. 02/06/2015)
2. The following submissions contain the appropriate mechanical testing for the VERTEX® Reconstruction System:
 - I. VERTEX® Reconstruction System K003780 (S.E. 09/28/2001)
 - II. VERTEX® Reconstruction System K022015 (S.E. 07/18/2002)
 - III. VERTEX® Reconstruction System K042498 (S.E. 10/07/2004)
 - IV. VERTEX® Reconstruction System K052402(S.E. 09/23/2005)
 - V. VERTEX® Reconstruction System K052376 (S.E. 01/05/2006)
 - VI. VERTEX® Reconstruction System K071942 (S.E. 12/11/2007)
 - VII. VERTEX® Reconstruction System K123906 (S.E. 04/01/2013)

VII. Performance Data:

The following performance data were provided in support of substantial equivalence.

The subject VERTEX® Reconstruction System implants are permanent implants and will be classified as permanent , >30 day body contact according to with 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 are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:

- ASTM F136-13: Standard Specification for Wrought Ti-6Al-4V ELI Alloy for Surgical Implant
- ASTM F67-13: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ASTM F1537-11: Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants
- ASTM F2063-12: Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants

VIII. Mechanical Testing

Due to the high degree of complexity in the allowable device configuration, a comprehensive computer simulation study was undertaken to identify the expected worst-case configuration. The computational study involved evaluating simple models (rods, screws, hooks) and adding additional components to create a more complex model. The computer simulations showed that heating generally decreased with increasing complexity of the Vertex constructs. Once the worst-case configurations were identified, these

constructs were physically tested in real MR scanners (both 1.5 and 3 T) to measure the actual heating observed during scanning.

In accordance with the FDA Guidance “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment” the subject VERTEX® Reconstruction System was evaluated for MR-safety in accordance with the following standards:

- ASTM F2052:2014 – “Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment”
- ASTM F2213:2006 (2011) – “Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment”
- ASTM F2119:2007 (2013) – “Standard test method for evaluation of MR image artifacts from passive implants”
- ASTM F2182:2002a, 2011, 2011a – “Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging”

The VERTEX® Reconstruction System has been labeled in accordance with ASTM F2503-13 “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.

IX. Conclusion:

The subject VERTEX® Reconstruction System was evaluated for MR-safety and compatibility. Additional testing was not performed on the VERTEX® Reconstruction System as no changes to the actual product are occurring. Therefore as no changes have occurred the subject device is considered substantially equivalent to the previously cleared 510(k) submission:

1. The following submission contains identical indications for use as the subject device:
 - i. Primary Predicate – VERTEX® Reconstruction System K143471 (S.E. 02/06/2015)
2. The following submissions contain the appropriate mechanical testing for the VERTEX® Reconstruction System:
 - i. VERTEX® Reconstruction System K003780 (S.E. 09/28/2001)
 - ii. VERTEX® Reconstruction System K022015 (S.E. 07/18/2002)
 - iii. VERTEX® Reconstruction System K042498 (S.E. 10/07/2004)
 - iv. VERTEX® Reconstruction System K052402(S.E. 09/23/2005)
 - v. VERTEX® Reconstruction System K052376 (S.E. 01/05/2006)
 - vi. VERTEX® Reconstruction System K071942 (S.E. 12/11/2007)
 - vii. VERTEX® Reconstruction System K123906 (S.E. 04/01/2013)

The VERTEX® Reconstruction System was determined to be MR-conditional.