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

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

August 21, 2017

Re: K163375
Trade/Device Name: INFINITY™ OCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: July 21, 2017
Received: July 24, 2017

Dear Mr. Patel:

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,

Katherine D. Kavlock
-S

for
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)*
K163375

Device Name
INFINITY™ OCT System

Indications for Use *(Describe)*

The INFINITY™ OCT 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.
- 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 INFINITY™ OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time 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 INFINITY™ OCT System may be connected to the CD HORIZON® Spinal System and VERTEX Reconstruction System rods with the INFINITY™ OCT System rod connectors. Transition rods with differing diameters may also be used to connect the INFINITY™ OCT System to the CD HORIZON® Spinal System. Refer to the CD HORIZON® Spinal System package insert and VERTEX Reconstruction System package insert for a list of the indications of use.

Note: The 3.0mm multi axial screw (MAS) requires the use of MAS CROSSLINK® at each level in which the 3.0mm screw is intended to be used.

The lateral offset connectors and MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws. The lateral offset connectors and MAS extension connectors are not intended to be used with 3.0mm screws.

Note: Segmental fixation is recommended for these constructs.

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.

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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

July 21, 2017

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

Contact: Tejas Patel
Sr. Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: tejaskumar.r.patel@medtronic.com

II. Proprietary Trade Name: INFINITY™ OCT System

Classification: Unclassified

Product Code: NKG, KWP

III. Predicate Device:
K143471 VERTEX® Reconstruction System (S.E.02/06/2015) – Primary Predicate
K003780 VERTEX® Reconstruction System (S.E. 09/28/2001)- Additional Predicates:
K052734 VERTEX® Reconstruction System (S.E. 10/21/2005)
K070742 VERTEX® Reconstruction System (S.E. 09/14/2007)
K071942 VERTEX® Reconstruction System (S.E. 12/11/2007)
K082728 VERTEX® Reconstruction System (S.E. 01/16/2009)
K090714 VERTEX® Reconstruction System (S.E. 04/17/2009)
K091365 VERTEX® Reconstruction System (S.E. 08/06/2009)
K123656 VERTEX® Reconstruction System (S.E. 02/25/2013)
K123906 VERTEX® Reconstruction System (S.E. 04/01/2013)
K152338 VERTEX® Reconstruction System (S.E.10/28/2015)
K162379 CD Horizon® Spinal System (S.E. 11/16/2016)
These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. Device Description:

The INFINITY™ OCT System is a posterior occipitocervical-upper thoracic 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, with each construct being tailor-made for the individual case.

The INFINITY™ OCT System is fabricated from medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium alloy and medical grade cobalt chromium may be used together.

The sole purpose for this traditional 510(k) is to seek clearance for the INFINTIY™ OCT System.

V. Indications for Use:

The INFINITY™ OCT 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.
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Note: Segmental fixation is recommended for these constructs.

VI. Comparison of Technological Characteristics with the Predicate devices:

As established in this submission, the subject INFINITY™ OCT System is substantially equivalent to the identified predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have equivalent technological characteristics to their predicate devices through comparison in areas including design, labeling/intended use, material composition, and function.

VII. Discussion of the Non-clinical Testing/Performance Data:

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 identified predicate devices. Design verification testing for the subject implants was completed in accordance with

- ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- ASTM F2706: Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model.

The tests completed were:

- Static Compression Bending
- Static Torsion Testing
- Dynamic Compression Bending
- Dynamic Torsion Testing

The mechanical testing verifies that the subject components are substantially equivalent to the predicate spinal system currently on the market and has met all mechanical testing requirements based on the worst case construct testing.

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. Conclusion:

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, and results of the mechanical testing, the subject INFINITY™ OCT System has been shown to be substantially equivalent to the legally marketed predicate devices cited in this summary.