January 11, 2023

Medtronic Sofamor Danek USA, Inc.
Ms. Laura Parr
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K223764
Trade/Device Name: INFINITY™ OCT System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: December 14, 2022
Received: December 15, 2022

Dear Ms. Parr:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223764

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.

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.

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510(k) Summary

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

Contact: Laura Beth Parr
Regulatory Affairs Specialist
Telephone Number: (901) 344-0614
Email: laurabeth.parr@medtronic.com

Date Prepared: December 14, 2022

II. Proprietary Trade Name: INFINITY™ OCT System

Common Name: Posterior cervical screw system

Classification Name: Posterior Cervical Screw System (21 CFR §888.3075)
Spinal Interlaminal Fixation Orthosis (21 CFR §888.3050)

Classification: Class II

Product Code: NKG, KWP

III. Predicate Devices:

Primary Predicate	INFINITY™ OCT System (K163375, S.E. 08/21/2017)
Additional Predicate	Vertex® Reconstruction System (K090714, S.E. 04/17/2009)

IV. Device Description:

The INFINITY™ OCT System is a posterior occipitocervical-upper thoracic system. The system consists of a variety of shapes and sizes of plates, rods, hooks, set 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. Per this 510(k) submission, Medtronic is seeking the clearance of new non-sterile multi-axial screws (MAS), axial dominos, and MAS extension connector that will be part of the INFINITY™ OCT System. These devices are identical in design and material to those cleared in K163375 (S.E. 08/21/2017) and there is only a change in sterility.

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.
- 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.

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.

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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.

VI. Comparison of Technological Characteristics with the Predicate devices:

As established in this submission, the subject INFINITY™ OCT System devices are substantially equivalent to the identified predicate devices cleared by the FDA for

commercial distribution in the United States. The subject devices are identical in design to the primary predicate devices and the only change is to the sterility of the devices. Because of sterility being the only change, 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, function, and sterilization.

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

The subject devices do not represent a new worst-case and the testing for the predicate devices is deemed applicable for the subject devices. The sterilization justification for the predicate devices adopts the subject devices into existing steam validation documents. The subject devices and the predicate devices have identical designs, materials, and manufacturing processes. Therefore, no additional bench performance testing is needed.

VIII. Conclusion

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