October 24, 2025

Medtronic Sofamor Danek USA, Inc.
Wafa Mustafa
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K253129
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, OLO
Dated: September 24, 2025
Received: September 25, 2025

Dear Wafa Mustafa:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253129

Please provide the device trade name(s).

Infinity™ OCT System

Please provide your Indications for Use below.

Infinity™ OCT System
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.
The Infinity™ OCT System may be used with PASS OCT Patient Specific UNiD OCT rods. 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, Vertex™ Reconstruction System and PASS OCT Spinal 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.

Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ POWEREASE™ Systems
Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

MEDTRONIC
Infinity™ OCT System
September 24, 2025

I. Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132
Contact Person	Wafa Mustafa Sr. Regulatory Affairs Specialist Email: wafa.mustafa@medtronic.com
II. Name of Device	Infinity™ OCT System
Common Name	Bone Screw, Powered Instrument
Classification Name	Posterior cervical screw system, Stereotaxic Instrument
Classification	Implants: Class II Instruments: Class II
Product Codes	Implants: NKG (888.3075) Instruments: OLO (882.4560)
III. Predicate Devices	**Primary Predicate:** 1. Infinity™ OCT System (K163375, S.E. 08/21/2017) **Additional Predicate:** 2. Navigated Infinity™ Instruments (K173338, S.E. 01/18/2018) *The predicates have not been subject to a design related recall.*

IV. Description	**Infinity™ OCT System** 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. **Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ POWEREASE™ Systems** Medtronic Navigated Reusable Instruments are spine preparation instruments manufactured from high grade stainless steel. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allows a Medtronic computer assisted surgery system such as the StealthStation™ Image Guidance System to track the instruments in the surgical field. Medtronic Navigated Reusable Instruments are compatible with various Medtronic spinal implant systems. These instruments are also compatible with Medtronic's IPC™ POWEREASE™ System when connected to the POWEREASE™ Driver.
V. Indications for Use	**Infinity™ OCT System** 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.

	The Infinity™ OCT System may be used with PASS OCT Patient Specific UNiD OCT rods. 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, Vertex™ Reconstruction System and PASS OCT Spinal 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. **Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ POWEREASE™ Systems** Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist 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.

VI. Comparison of Technological Characteristics with the Predicate Devices	The subject devices have the same intended use, indications for use, materials, similar overall design, fundamental technology, sterilization, and surgical technique as the Infinity™ OCT System and Navigated Infinity™ Instruments predicates: • K163375, S.E. 08/21/2017 • K173338, S.E. 01/18/2018 The subject and predicate implants and instruments have the same function and fundamental scientific technology.
VII. Performance Data	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. The subject devices have been tested or rationalized based on if Medtronic believes that testing is not warranted for the subject devices as they do not present a new worst case when compared to the predicates. Testing and/or Rationales were completed for the following: • ASTM F1717: Static Compression, Static Torsion, Compression Fatigue For the tested subject devices, the pre-determined acceptance criteria was met for all tests. For subject devices that are rationalized, all existing predicate data previously provided in the predicate 510(k)s is still applicable. Design validation has also been performed and demonstrated that the subject devices performed as intended. Therefore, Medtronic believes the design verification and validation testing demonstrated that the subject devices are substantially equivalent to the predicate devices.
VIII. Conclusion	Based on the supporting evidence provided in this premarket notification, Medtronic believes the subject devices are substantially equivalent to the predicate devices.