March 18, 2021

Medtronic Sofamor Danek, USA Inc.
Shweta Sharma
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K210449
Trade/Device Name: Infinity™ OCT System, PASS OCT® Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: February 11, 2021
Received: February 16, 2021

Dear Shweta Sharma:

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,

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)*
K210449

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.
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.

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.

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)*
K210449

Device Name
PASS OCT® Spinal System

Indications for Use *(Describe)*
The PASS OCT® Spinal 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 PASS OCT® Spinal 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 PASS OCT® Spinal System may be linked to the PASS LP® Spinal System using the dual diameter rods or specific connecting components.
The PASS OCT® Patient Specific Rod is to be implanted either with PASS OCT® Spinal System or with Infinity™ OCT Spinal System.
Warning: mixing PASS OCT® and Infinity OCT Spinal Systems connection components is not allowed for the PASS OCT® Patient Specific Rod implantation, as the operating principle for screw attachment or fixation is unsimilar between the two systems and will cause a misalignment of the rod. Mixing lateral loading screw system and top loading screw system is prohibited.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of lower thoracic (T4-T12), or lumbar spine.
CAUTION: to be used by or according to the prescription of a licensed physician.
Implantation should only be performed by a surgeon who is familiar with the device, its intended use, dedicated instruments, and understands all aspects of the surgical procedure.

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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PRAStaff@fda.hhs.gov

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510(k) SUMMARY

11th February 2021

I. Company: Medtronic Sofamor Danek, USA Inc.
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Memphis, TN 38132
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Contact: Shweta Sharma
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Proprietary Trade Name: Infinity™ OCT System
PASS OCT® Spinal System

Classification Name/	Posterior Cervical Screw System
Regulation Numbers/	21 CFR§ 888.3075
Classification/	Class II
Classification Product Code/Subsequent Product Codes	NKG KWP

II. Predicate Devices:

Primary Predicate:

Infinity™ OCT System (K163375; S.E. 08/21/2017)

Additional Predicate:

PASS OCT® Spinal System (K153169; S.E. 01/29/2016)

These predicate devices have not been subject to a design-related recall.

III. Device Description:

The purpose of this submission is to expand the use of previously cleared Infinity™ OCT System with previously cleared PASS OCT® Patient Specific UNiD OCT Rods.

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. Medical grade titanium alloy and medical grade cobalt chromium may be used together.

PASS OCT® Spinal System

The PASS OCT® Spinal System is a posterior system, which consists of a variety of shapes and sizes of rods, hooks, polyaxial screws, occipital plates, occipital bone screws, and connection components, which can be rigidly locked to the rod in a variety of configurations.

The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, Grade Titanium conforming to ASTM F67 and ISO 5832-2, Cobalt-chromium molybdenum alloy Co-Cr28Mo6 according to ISO 5832-12 and ASTM F1537 and in PEEK OPTIMA LT1 conforming to ASTM F2026 specifications.

The PASS OCT® Patient Specific Rod has been designed and manufactured for one specific patient. The PASS OCT® Patient Specific Rod should be used during surgery for this patient only and should not be reused (single use only).

Refer to the surgical technique for additional information. If the PASS OCT® Patient Specific Rod does not perform as intended, use the standard PASS OCT® rod or Infinity™ OCT rod to complete the surgery.

As any orthopaedic implant, these implants must not be reused. For a complete guide to the system, it is important to refer to the surgical technique.

IV. 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 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.

PASS OCT® Spinal System

The PASS OCT® Spinal 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 PASS OCT® Spinal 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 PASS OCT® Spinal System may be linked to the PASS LP® Spinal System using the dual diameter rods or specific connecting components.

The PASS OCT® Patient Specific Rod is to be implanted either with PASS OCT® Spinal System or with Infinity™ OCT Spinal System.

Warning: mixing PASS OCT® and Infinity OCT Spinal Systems connection components is not allowed for the PASS OCT® Patient Specific Rod implantation, as the operating principle for screw attachment or fixation is unsimilar between the two systems and will cause a misalignment of the rod. Mixing lateral loading screw system and top loading screw system is prohibited.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of lower thoracic (T4-T12), or lumbar spine.

Caution: To be used by or according to the prescription of a licensed physician.

Implantation should only be performed by a surgeon who is familiar with the device, its intended use, dedicated instruments, and understands all aspects of the surgical procedure.

V. Comparison of the Technological Characteristics with the Predicate Device:

When using the PASS OCT® System Patient Specific UNiD OCT Rods and the Infinity OCT System together; there is no change to the fundamental scientific technology, indications for use, intended use, materials, and levels of attachment as the predicate Infinity™ OCT System devices and PASS OCT® Spinal System UNiD OCT rods.

The difference between the primary predicate and subject devices is that rods currently used with the predicate Infinity™ OCT System are cut and bent by the surgeon based on the need of the individual case, while the PASS OCT® System UNiD OCT Rods are directly adapted to a unique patient. However, both the subject and predicate systems are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical, cervical, and/or upper thoracic spine (occiput-T3).

VI. 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.

Rationales were provided confirming that the use of the PASS OCT® System Patient Specific UNiD OCT Rods did not introduce a new worst case when used with the Infinity™ OCT System. However, confirmatory testing (static and dynamic compression bending and static and dynamic torsion per ASTM F1717) performed met the pre-determined acceptance criteria. Therefore, Medtronic believes that the testing confirmed that the subject devices are substantially equivalent to the predicate devices.

VII. Conclusions

Based on the test results and supporting information provided in this premarket notification, Medtronic believes the Infinity™ OCT System devices when used with the PASS OCT® System Patient Specific UNiD OCT Rods are at least as safe as and effective as the legally marketed predicate devices.