December 13, 2021

Medtronic Sofamor Danek
Diamond Wallace
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K212428
Trade/Device Name: CENTERPIECE™ Plate Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: November 8, 2021
Received: November 10, 2021

Dear Diamond Wallace:

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)*
K212428

Device Name
CENTERPIECE™ Plate Fixation System

Indications for Use *(Describe)*

The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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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510(k) SUMMARY

November 5th, 2021

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

Contact: Diamond Wallace
Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: diamond.m.wallace@medtronic.com

II. Proprietary Trade Name: CENTERPIECE™ Plate Fixation System

Common Name: Appliance, Fixation, Interlaminal

Classification Name: 21 CFR 888.3050 - Spinal interlaminal fixation orthosis

Classification: Class II

Product Code: NQW

III. Predicate Devices:

Primary Predicate:
CENTERPIECE™ Plate Fixation System (K050082, S.E. 06/06/2005)

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

IV. Device Description:

The CENTERPIECE™ Plate Fixation System consists of a variety of sizes of plates and screws. The CENTERPIECE™ Plate Fixation System screws are made of from medical grade titanium or titanium alloy. Screws will be provided sterile and non-sterile and are reusable.

V. Indications for Use:

The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE TM Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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

CENTERPIECE™ Plate Fixation System has the same fundamental scientific technology; indications for use, intended use, design, material levels of attachment as the predicate device. The predicate and subject devices are intended to restore spine stability and improve fusion.

VII. Performance Data:

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description
Static Compression	The purpose of this testing was to compare the static compression properties of the CENTERPIECE™ subject and predicate screw-plate constructs. A compressive load was applied to the construct in the posterior to anterior direction to simulate in vivo loading conditions.
MRI Safety Evaluation	The purpose of this testing was to evaluate the MRI safety of the CENTERPIECE™ Plate Fixation System.
Pull Out Strength Evaluation	The purpose of this engineering rationale was to address pullout strength testing of the CENTERPIECE™ Plate Fixation System.

VIII. Conclusions

The CENTERPIECE™ Plate Fixation System implants have shown through comparison and testing to be substantially equivalent to the identified predicate devices.