Medtronic Sofamor Danek USA, Inc.
Scott Baker
Sr. Regulatory Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

June 15, 2023

Re: K231090
Trade/Device Name: ZEVO™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 13, 2023
Received: April 17, 2023

Dear Scott Baker:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.06.15 12:59:39 -04'00'

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)*
K231090

Device Name
ZEVO™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The ZEVO™ Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

ZEVO™ Anterior Cervical Plate System
510(k) Summary
April 13, 2023

I.	**Company:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 (901) 396-3133
II.	**Contact:**	Scott P. Baker Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	ZEVO™ Anterior Cervical Plate System
IV.	**Common Name:**	Spinal Intervertebral Body Fixation Appliance
V.	**Classification Name:**	21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis
	Classification:	Class II
	Product Codes:	KWQ

VI. Product Description:

The ZEVO™ Anterior Cervical Plate System consists of temporary implants (plates and bone screws) intended for anterior screw fixation of the cervical spine during the development of a cervical spinal fusion. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The device is intended for the anterior screw fixation from C2- T1 in the cervical spine.

The ZEVO™ Anterior Cervical Plate System implants are available in a broad range of size offerings, and are supplied in both sterile and non-sterile form.

The implant components are made from titanium alloy, with plates having subcomponents manufacturing from nitinol (NiTi).

The purpose of this submission is to establish MR Conditional labeling for this implant system.

VII. Indications for Use:

The ZEVO™ Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis, 5) pseudoathrosis, and/or 6) failed previous fusions.

VIII. Summary of Technological Characteristics

The subject devices do not differ from the technological characteristics of the predicate devices.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

The subject plate and bone screws are substantially equivalent to the primary predicate: ZEVO Anterior Cervical Plate System K141632 (S.E. 12/04/2014)

X. MR safety Testing

In accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the subject Medtronic Anterior Cervical Plate Systems were evaluated for MR-safety in accordance with the following standards:

- RF-Induced heating: ASTM F2182-19e2
- Magnetically Induced Force: ASTM F2052-21
- Magnetically Induced Torque: ASTM F2213-17
- Image Distortion: ASTM F2119-07(2013)
- Labelling: ASTM F2503-20

Conclusions Drawn from the Non-Clinical Tests

Based on the non-clinical test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the listed predicate devices.