February 6, 2019

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

Re: K182885
Trade/Device Name: Atlantis™ Anterior Cervical Plate, Divergence™ Anterior Cervical Fusion System, Premier™ Anterior Cervical Plate, Venture™ Anterior Cervical Plate, Zephir™ Anterior Cervical Plate System and 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, OVE, ODP
Dated: January 15, 2019
Received: January 16, 2019

Dear Ms. Hines:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182885

Device Name
Atlantis™ Anterior Cervical Plate, Divergence™ Anterior Cervical Fusion System, Premier™ Anterior Cervical Plate, Venture™ Anterior Cervical Plate, Zephir™ Anterior Cervical Plate System and Zevo™ Anterior Cervical Plate System

Indications for Use *(Describe)*

Atlantis™ Anterior Cervical Plate System:
Properly used, this system is intended for anterior interbody screw fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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.
Nota bene: this device system is intended for anterior cervical intervertebral body fusions only.
Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Divergence™ Anterior Cervical Fusion System:
The Divergence™ anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. Plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of spinal fusions in patients with: 1) degenerative disc disease (DDD - 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) pseudoarthrosis; and/or 6) failed previous fusions.

The Divergence™ anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from C2-C3 to C7-T1. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non operative treatment. The Divergence™ cage must be used with supplemental fixation. The Divergence™ cage is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

When used together, the Divergence™ components can be used only to treat cervical disc disease.

Divergence™ Anterior Cervical Fusion System (Stand-Alone Interbody)
The Divergence™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from C2-C3 to C7-T1. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Divergence™ stand-alone cervical interbody device must be used with internal screw fixation. The Divergence™ stand-alone cervical interbody device is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Premier™ Anterior Cervical Plate System:
Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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.
Nota bene: this device system is intended for anterior cervical intervertebral body fusions only.
Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Venture™ Anterior Cervical Plate System:
Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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.
Nota bene: this device system is intended for anterior cervical intervertebral body fusions only.

Zephir™ Anterior Cervical Plate System:
Properly used, this system is intended for anterior interbody screw/plate fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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.
Nota bene: this device system is intended for anterior cervical intervertebral body fusions only.
Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Zevo™ Anterior Cervical Plate System:
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 development of cervical spinal fusions in patients with: 1) degenerative disc disease (DDD - 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.
Nota bene: this device system is intended for anterior cervical intervertebral body fusions only.
Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek
MRI Update for Medtronic Anterior Cervical Plate Systems

January 2019

Submitter:	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Kanesha Hines Regulatory Affairs Specialist Direct Telephone: (901)399-2670
Date Prepared	January 15, 2019
Name of Device	Medtronic Anterior Cervical Plate and Fusion Systems (Atlantis™ Anterior Cervical Plate, Divergence™ Anterior Cervical Fusion System, Premier™ Anterior Cervical Plate, Venture™ Anterior Cervical Plate, Zephir™ Anterior Cervical Plate System and Zevo™ Anterior Cervical Plate System)
Common Name	Appliance, Fixation, Spinal Intervertebral Body
Trade Name	Atlantis™ Anterior Cervical Plate, Divergence™ Anterior Cervical Fusion System, Premier™ Anterior Cervical Plate, Venture™ Anterior Cervical Plate, Zephir™ Anterior Cervical Plate System and Zevo™ Anterior Cervical Plate System
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	• Class II • 21 CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis; KWQ, • 21 CFR 888.3080 Intervertebral body fusion device OVE, ODP
Predicate Devices	• Primary Predicate 1- K152623 Atlantis™ Anterior Cervical Plate System (S.E 11/12/2015) • Predicate 2- K130640 Atlantis™ Anterior Cervical Plate System (S.E 06/04/2013) • Predicate 3- K081038 Atlantis™ Anterior Cervical Plate System (S.E 08/15/2008) • Predicate 4- K063100 Atlantis™ Anterior Cervical Plate System (S.E 02/23/2007) • Predicate 5- K021461 Atlantis™ Anterior Cervical Plate System (S.E 07/22/2002)

	• Predicate 6- K970806 Atlantis™ Anterior Cervical Plate System (S.E 05/02/197) • Predicate 7- K140417 Divergence™ Anterior Cervical Fusion System (S.E. 07/09/2014) • Predicate 8- K141599 Divergence™ Anterior Cervical Fusion System (S.E. 01/21/2015) • Predicate 9- K021761 Premier™ Anterior Cervical Plate System (S.E 09/17/2002) • Predicate 10- K992110 Premier™ Anterior Cervical Plate System (S.E 09/14/1999) • Predicate 11- K061274 Venture™ Anterior Cervical Plate System (S.E 05/25/2006) • Predicate 12- K042922 Venture™ Anterior Cervical Plate System (S.E 11/19/2004) • Predicate 13- K030327 Zephir™ Anterior Cervical Plate System (S.E. 02/26/2003) • Predicate 14- K994239 Zephir™ Anterior Cervical Plate System (S.E. 06/19/2000) • Predicate 15- K141632 Zevo™ Anterior Cervical Plate System (S.E. 12/04/2014) *The predicates have not been subject to a design related recall.*
Description of Devices	The Medtronic Anterior Cervical Plate Systems consist of a variety of shapes and sizes of bone plates (set screws and washers are pre-assembled to the plates) and screws. The Medtronic Anterior Cervical Fusion System consist of variety of shapes and sizes of bone plates (set screws and washers are pre-assembled to the plates), interbody cages, and screws. Fixation is provided by bone screws and/or interbody cages inserted into the vertebral body of the cervical spine using an anterior approach. The Medtronic Anterior Cervical Plate and Fusion Systems implant components are made from titanium alloy, with certain plates having subcomponents manufactured from shape memory alloys (Nitinol-NiTi). The sole purpose for this submission is to update the labeling for the Medtronic Anterior Cervical Plate and Fusion Systems to include MRI safety information while also providing MRI technologists with a method of concluding whether a MRI scan can be performed and specific instructions on how to perform the scan.
Indications for Use	<u>Atlantis™ Anterior Cervical Plate System:</u> Properly used, this system is intended for anterior interbody screw fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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. Nota bene: this device system is intended for anterior cervical intervertebral body fusions only. Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. <u>Divergence™ Anterior Cervical Fusion System:</u> The Divergence™ anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. Plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of spinal fusions in patients with: 1) degenerative disc disease (DDD - 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) pseudoarthrosis; and/or 6) failed previous fusions. The Divergence™ anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from C2-C3 to C7-T1. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non operative treatment. The Divergence™ cage must be used with supplemental fixation. The Divergence™ cage is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach. When used together, the Divergence™ components can be used only to treat cervical disc disease.

	Divergence™ Anterior Cervical Fusion System (Stand-Alone Interbody) The Divergence™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from C2-C3 to C7-T1. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Divergence™ stand-alone cervical interbody device must be used with internal screw fixation. The Divergence™ stand-alone cervical interbody device is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Premier™ Anterior Cervical Plate System: Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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. Nota bene: this device system is intended for anterior cervical intervertebral body fusions only. Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Venture™ Anterior Cervical Plate System: Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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. Nota bene: this device system is intended for anterior cervical intervertebral body fusions only. <u>Zephir™ Anterior Cervical Plate System:</u> Properly used, this system is intended for anterior interbody screw/plate fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. 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 (DDD - 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. Nota bene: this device system is intended for anterior cervical intervertebral body fusions only. Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. <u>Zevo™ Anterior Cervical Plate System:</u> 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 development of cervical spinal fusions in patients with: 1) degenerative disc disease (DDD - 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. Nota bene: this device system is intended for anterior cervical intervertebral body fusions only. Warning: this device is not approved for screw attachment to posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Comparison of Technological Characteristics with the Predicate Devices:	The subject devices do not differ from the technological characteristics of the predicate devices.
Performance Data:	The following performance data were provided in support of

	substantial equivalence. **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: • ASTM F2052– "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment" • ASTM F2213– "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment" • ASTM F2119– "Standard test method for evaluation of MR image artifacts from passive implants" • ASTM F2182– "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging" The Medtronic Anterior Cervical Plate Systems has been labeled in accordance with ASTM F2503 "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment".
Conclusion:	Based on the supporting documentation provided in this pre-market notification, the subject Anterior Cervical Plate Systems are as safe and effective as the following predicates: • Atlantis™ Anterior Cervical Plate (K152623 S.E. 11/12/2015, K130640 S.E 06/04/2013, K081038 S.E 08/15/2008, K063100 S.E 02/23/2007, K021461 S.E 07/22/2002, K970806, S.E. 05/02/1997) • Divergence™ Anterior Cervical Fusion System (K140417, S.E. 07/09/2014, K141599, S.E. 01/21/2015) • Premier™ Anterior Cervical Plate (K021761, S.E. 09/17/2002, K992110, S.E. 09/14/1999) • Venture™ Anterior Cervical Plate (K061274 S.E. 05/25/2006, K042922 S.E. 11/19/2004) • Zephir™ Anterior Cervical Plate System (K030327 S.E. 02/26/2003, K994239 S.E. 06/19/2000) • Zevo™ Anterior Cervical Plate System (K141632 S.E. 12/04/2014)