DIVERGENCE™ Anterior Cervical Fusion System
510(k) Summary

9 July 2014

I.	**Company:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 (901) 396-3133
II.	**Contact:**	Shweta Sharma Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	DIVERGENCE™ Anterior Cervical Fusion System
IV.	**Common Name:**	Spinal Intervertebral Body Fixation Appliance, Cervical Intervertebral Fusion Device with Bone Graft
V.	**Classification Name:**	21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3080 - Intervertebral Body Fusion Device
	Classification:	Class II
	Product Codes:	KWQ, ODP

VI. Product Description:

The DIVERGENCE™ Anterior Cervical Fusion System consists of temporary implants (plates and bone screws) intended for anterior screw fixation, and fusion devices (interbody cages) intended to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The DIVERGENCE™ anterior cervical plates and bone screws are available in broad range of size offerings that are intended for anterior screw fixation intended for

stabilization use during the normal healing process following surgical correction of disorders of the spine. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The DIVERGENCE™ anterior cervical plate and bone screws are made from titanium alloy and are provided sterile.

The DIVERGENCE™ anterior cervical cages available in various widths and heights can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants must be used with supplemental fixation. The device is made from medical grade polyetheretherketone (PEEK OPTIMA™), contains titanium alloy wire markers and is provided sterile.

VII. Indications for Use:

The DIVERGENCE™ anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The 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 (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 the C2-C3 disc to the C7-T1 disc. 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.

VIII. Summary of Technological Characteristics

The subject DIVERGENCE™ Anterior Cervical Fusion System plate and bone screw components have the same fundamental scientific technology as the predicate ZEPHIR® Anterior Cervical System and ATLANTIS® Anterior Cervical System devices. The subject devices are manufactured from the same titanium alloy material as the predicates. The predicate and subject devices are also both anterior screw fixation devices where fixation is provided by bone screws inserted into the vertebral body of the cervical spine.

The subject DIVERGENCE™ Anterior Cervical Fusion System interbody cage component has the same fundamental scientific technology as the predicate ANATOMIC PEEK Cervical Fusion System, CORNERSTONE® PSR Cervical Fusion System, PEEK PREVAIL® Cervical Interbody Device, AFFINITY® Anterior Cervical Cage System and PERIMETER® C spinal system devices. The subject interbody cage is manufactured from the same PEEK and titanium alloy material as the predicate devices. The predicate and subject devices are also both interbody devices designed to contain graft material and facilitate a fusion between two vertebral bodies.

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

The subject mini plate and bone screws are substantially equivalent to the predicates:

- ZEPHIR® Anterior Cervical System (K030327, SE 02/26/03)
- ATLANTIS® Anterior Cervical Plate System (K130640, SE 06/04/13)

The subject interbody cage is substantially equivalent to the predicates:

- ANATOMIC PEEK Cervical Fusion System (K130177, SE 09/23/13; K112444, SE 11/15/11)
- CORNERSTONE® PSR Cervical Fusion System (K111264, SE 10/12/11)
- PEEK PREVAIL® Cervical Interbody Device (K113252, SE 1/17/12; K094042, SE 06/30/10)
- AFFINITY® Anterior Cervical Cage System (P000028, Approval Date 07/13/02, down-classified to Class II special controls, Date of Final Order 06/12/07)
- PERIMETER® C Spinal System (K132584, SE 12/04/13; K100967, SE 08/05/11)

X. Brief Discussion of the Non-Clinical Tests Submitted

The subject DIVERGENCE™ Anterior Cervical Fusion System devices were tested in accordance to ASTM F1717-13 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model", ASTM F2077-11 "Test Methods For Intervertebral Body Fusion Devices" and ASTM F2267-04(2011) "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression".

The subject devices met the pre-determined acceptance criteria for all the tests. The test results are provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

XI. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 9, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Shweta Sharma
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K140417
Trade/Device Name: DIVERGENCE™ Anterior Cervical Fusion System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ, ODP
Dated: June 12, 2014
Received: June 13, 2014

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140417

Device Name
DIVERGENCE™ Anterior Cervical Fusion System

Indications for Use *(Describe)*

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. The 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 (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 the C2-C3 disc to the C7-T1 disc. 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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