DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

June 11, 2015

Re: K150135
Trade/Device Name: DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, KWQ
Dated: May 13, 2015
Received: May 14, 2015

Dear Ms. Joe:

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" (21CFR 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,

Mark N. Melkerson -S

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)*
K150135

Device Name
DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Indications for Use *(Describe)*

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody is indicated for interbody fusion in patients with DDD at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion Interbody cage is also required to be used with autogenous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine. Interbody cages with a lordosis of 18º or greater must be used with at least supplemental, anterior fixation.

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation (L5-S1) of the vascular structures or anterior oblique above the bifurcation (L1-L5) of the vascular structures. 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 lumbar spine during the development of spinal fusions in patients with: 1) Degenerative Disc Disease (DDD) defined by back 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.

When used together, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System components can be used only to treat patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System
510(k) SUMMARY
June 09, 2015

I. Submitter

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901)396-3133

Contact

Lila Joe
Principle Regulatory Affairs Specialist

Date Prepared

June 09, 2015

II. Device

Name of Device

DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Classification Name

Intervertebral Body Fusion Device
(21 CFR 888.3080)

Intervertebral Body Fusion Device
(21 CFR 888.3080)

Spinal Intervertebral Body Fixation Orthosis
(21 CFR 888.3060)

Classification

Class II

Product Codes

KWQ (Plates and Screws)

MAX, OVD (Interbody Cages)

Predicates

Primary Predicate

PERIMETER® Interbody Fusion Device
K131669 (S.E. 11/01/2013)

Additional Predicates

- CAPSTONE® Spinal System
  K133650 (S.E. 12/26/2013)
- CLYDESDALE® Spinal System
  K132897 (S.E. 12/11/2013)

- CAPSTONE CONTROL
  K120368 (S.E. 04/09/2012)
- LT CAGE® PEEK Lumbar Tapered Fusion Device
  (P970015/R022 - Approved 09/10/2003 -Downclassed)
- SOVEREIGN® Spinal System
  K122037 (S.E. 03/22/2013)
- CoRoent® XLR Standalone System
  K100043 (S.E. 06/13/2010)
- BRIGADE® Hyperlordotic System
  K123045 (S.E. 04/16/2013)
- PYRAMID® +4 Anterior Lumbar Plate System
  K071416 (S.E. 11/01/2007)
- ZPLATE II™ Anterior Fixation System
  K991460 (S.E. 05/19/1999).
- Reference Predicate
  DIVERGENCE™ Anterior Cervical Fusion System
  K142450 (S.E. 10/01/2014**)**

The predicates have not been subject to a design related recall.

III. Product Description

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System consists of plates, bone screws, and interbody cages.

The DIVERGENCE-L™ Anterior/Oblique Lumbar interbody cages are available in various widths, heights, and lordosis inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and must be used with supplemental fixation. The cages are manufactured from medical grade Polyetheretherketone (PEEK) and titanium alloy with tantalum markers and are provided sterile.

The DIVERGENCE-L™ Anterior/Oblique Lumbar plates and bone screws are available in a broad range of size offerings intended for anterior screw fixation and stabilization 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 lumbar spine using an anterior or oblique approach. The DIVERGENCE-

L™ Anterior/Oblique Lumbar plate and bone screws are made from titanium alloy and are provided sterile.

The subject devices are manufactured from *ASTM F2026 - Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications, ASTM F136 - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications, and ASTM F560 - Standard Specification for Unalloyed Tantalum for Surgical Implant Applications*.

The subject interbody cages, plates, and bone screws are implants that are single use only. The subject implants are provided sterile by gamma irradiation.

The subject instruments are reusable and provided non-sterile. The subject instruments must be cleaned and sterilized by the hospital.

IV. Indications for Use:

The DIVERGENCE-L Anterior/Oblique Lumbar Fusion System Interbody is indicated for interbody fusion in patients with DDD at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The DIVERGENCE-L™ cage is also required to be used with autogenous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine. Interbody cages with a lordosis of 18º or greater must be used with at least supplemental, anterior fixation.

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion plate and bone screws components are indicated as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation (L5-S1) of the vascular structures or anterior oblique above the bifurcation (L1-L5) of the vascular structures. 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 lumbar spine during the development of spinal fusions in patients with: 1) Degenerative Disc Disease (DDD) defined by back 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.

When used together, the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System components can be used only to treat patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels.

V. Comparison of Technological Characteristics

The primary predicate for the DIVERGENCE-L™ Anterior/Oblique Fusion Lumbar System is the PERIMETER® Interbody Fusion Device (K131669, S.E. 11/01/2013)

The subject DIVERGENCE-L™ Anterior/Oblique Fusion Lumbar interbody cages have the same or similar indications, intended use, fundamental scientific technology, and similar materials as the following FDA cleared predicates K131669 (S.E. 11/01/2013), K133650 (S.E. 12/26/2013), K132897 (S.E. 12/11/2013), K120368 (S.E. 04/09/2012), P970015/R022 (Approved 09/10/2003 - Downclassed), K122037 (S.E. 03/22/2013), K100043 (S.E. 06/13/2010), and K123045 (S.E. 04/16/2013).

The subject DIVERGENCE-L™ Anterior/Oblique Fusion Lumbar plates and bone screws have the same intended use, fundamental scientific technology, material, and similar indications as the following FDA cleared predicates K071416 (S.E. 11/01/2007) and K991460 (S.E. 05/19/1999).

The DIVERGENCE™ Anterior Cervical Fusion System (K142450 - S.E. 10/01/2014) is a cage and plate system. The DIVERGENCE™ Anterior Cervical Fusion System is not a part of this submission and is only mentioned to show that the subject DIVERGENCE-L™ Anterior/Oblique Fusion System is not the first cage and plate system to be legally marketed.

VI. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the subject DIVERGENCE-L™ Anterior/Oblique Fusion System interbody cages, plates, and bone screws was conducted in accordance with the FDA's Draft Guidance for Industry and FDA Staff, *Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing,* issued April 23, 2013.

The subject devices are manufactured from *ASTM F2026: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications, ASTM F136: Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications, and ASTM F560: Standard Specification for Unalloyed Tantalum for Surgical Implant Applications.*

The subject plates, bone screws, and interbody cages are permanent implants and will be classified as "Implant Devices - Tissue/bone - C Permanent (>30 days)" according to FDA's Draft Guidance for Industry and FDA Staff, *Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

Polyetheretherketone (PEEK), titanium alloy, and tantalum have a long history of safe and effective use in predicate spinal implants. Therefore, biocompatibility testing is not required.

The subject trials, inserters, and interbody remover are manufactured from:

- Silicone (Elastosil® liquid silicone rubber)
- medical grade stainless steel per
    - *ASTM A564, Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes,* or
    - *ASTM F899, Standard Specification for Wrought Stainless Steel for Surgical Instruments*

The subject instruments are classified as limited, up to 24 hours of body contact according to FDA's Draft Guidance for Industry and FDA Staff: *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, issued April 23, 2013.

The silicone rubber is used to manufacture instrument handles, which are non-patient contacting. Therefore, biocompatibility testing is not required according to FDA's Draft Guidance for Industry and FDA Staff: Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing, issued April 23, 2013.

Medical grade stainless steel has a long history of safe and effective use in spinal surgery and biocompatibility testing is not required.

Mechanical Testing

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.

Design verification testing was completed in accordance with

- *ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*,
- *ASTM F2077, Test Methods for Intervertebral Body Fusion Devices*
- *ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*
- *ASTM F-04.25.02.02, Static Push-out Test Method for Intervertebral Body Fusion Devices*

The tests completed were:

- Construct Static Compression
- Construct Compression Fatigue
- Construct Static Torsion
- Static Push-Out
- Static Compression
- Static Compression Shear
- Compression-Shear Fatigue
- Subsidence
- Expulsion

The subject devices with pre-determined acceptance criteria met the acceptance criteria for all tests. Expulsion testing for the PERIMETER® Interbody Fusion Device and the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion 24º lordosis interbody cage were performed as a characterization test and did not include pre-determined acceptance criteria.

VII. Conclusions

Design verification testing was completed in accordance with *ASTM F1717, ASTM F2077, ASTM F2267, and ASTM F-04.25.02.02.* Based on the test results and additional supporting information provided in this pre-market notification, Medtronic believes the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.