May 19, 2017

Medtronic Sofamor Danek USA, Inc.
Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K162212
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, KWQ
Dated: April 13, 2017
Received: April 20, 2017

Dear Mr. Grant:

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,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K162212

Device Name

DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Indications for Use (Describe)

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System interbody device is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use in 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the DIVERGENCE-L™ Interbody device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non-operative treatment. The DIVERGENCE-L™ Interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

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.

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."

FORM FDA 3881 (8/14)
DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

510(k) SUMMARY – K162212
May 2017

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

Contact
Lee Grant
Distinguished Regulatory Affairs Advisor

Date Prepared
May 16, 2017

II. Device

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

Classification Name
Intervertebral Body Lumbar Fusion Device with Bone Graft
(CFR 888.3080)

Intervertebral Body Lumbar Fusion Device
(CFR 888.3080)

Spinal Intervertebral Body Fixation Orthosis
(CFR 888.3060)

Classification
Class II

Product Codes
MAX (Interbody Cages)
KWQ (Plates and Screws)

Predicates
Primary Predicate
CLYDESDALE® Spinal System
K133577 (S.E. 09/26/2014 – Primary Predicate)

DIVERGENCE-L™ Anterior/Oblique Fusion System
K150135 (S.E. 06/11/2015 – Secondary Predicate)

CAPSTONE®/CLYDESDALE® Spinal System
K151128 (S.E. 08/06/2015 – Secondary Predicate)

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 autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. 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 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 device is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use in 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the DIVERGENCE-L™ Interbody device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non-operative treatment. The DIVERGENCE-L™ Interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.
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.

V. Summary of Technological Characteristics
The subject devices found within this submission have the same fundamental scientific technology as their predicate counterparts. They are intended to provide correction and stabilization during intervertebral body fusion procedures for the aforementioned indications. They are all manufactured from the same materials as their respective predicates and there have been no changes to the implants’ designs. With the exception of the expanded indication to include deformity conditions and the inclusion of the allogenic bone graft material option, there have been no changes to subject DIVERGENCE-L™ Anterior/Oblique Fusion Lumbar System’s offerings and they are therefore substantially equivalent to their predicates.

VI. Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing:
Published retrospective clinical data for the lumbar interbody fusion devices similar to the DIVERGENCE-L™ device is being provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft in interbody fusion procedures to treat the patient population referenced in the indications statement, poses no new risks to the patients. Additionally, the usage of similar devices to provide anterior column support when used as an adjunct to pedicle screw fixation in the treatment of deformity conditions was also found to pose no new risks to the patients. No changes were made to the existing devices, nor were any new components added to the systems. Therefore, no additional testing was required or performed.

VII. Non-Pyrogenicity Endotoxin Testing:
The bacterial endotoxin test, also known as Limulus Amebocyte Lysate (LAL) test, was performed utilizing worst case subject DIVERGENCE-L™ interbody implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.
VIII. Conclusions
The subject DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System is substantially equivalent to the primary predicate devices cleared in K133577 for the CLYDESDALE® Spinal System and to the additional predicate, K150135 application, for the original DIVERGENCE-L™ device as well as to both CAPSTONE®/CLYDESDALE® Spinal System application K151128. The published clinical outcomes demonstrate these devices may be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Additionally, the subject interbody devices may also be used to provide anterior column support in patients diagnosed with deformity conditions as an adjunct to pedicle screw fixation. Based on the outcomes presented in the literature review and comparisons to the three predicate applications presented in this pre-market notification, Medtronic believes the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.