



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

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

November 13, 2015

Re: K152277

Trade/Device Name: PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX, OVD, KWQ  
Dated: October 9, 2015  
Received: October 13, 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 Parts 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

## Indications for Use

510(k) Number (if known)

K152277

K152277

Page 1 of 1

Device Name

PIVOX™ Oblique Lateral Spinal System

Indications for Use (Describe)

The PIVOX™ Oblique Lateral Spinal System Interbody Cage is designed to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The PIVOX™ Oblique Lateral Spinal System interbody cage is used for patients diagnosed with DDD at one or two contiguous levels from L2 to S1. 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 PIVOX® Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach.

The PIVOX™ Oblique Lateral Spinal System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral levels, anterior below the bifurcation (L5-S1) of the vascular structures, and oblique or lateral above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be 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 PIVOX™ Oblique Lateral Spinal System components can be used to treat 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.

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)

**PIVOX® Oblique Lateral Spinal System**  
**510(k) SUMMARY**  
**November 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** November 12, 2015
- II. Device**
- Name of Device** PIVOX™ Oblique Lateral Spinal System
- Classification Name** Intervertebral Body Lumbar Fusion Device with Bone Graft (CFR 888.3080)  
  
Spinal Intervertebral Body Fixation Orthosis (CFR 888.3060)
- Classification** Class II
- Product Codes** MAX, OVD (Interbody Cages)  
  
KWQ (Plates and Screws)
- Predicates** There are 7 Predicates.
- Primary Predicate
- DIVERGENCE™-L™ Anterior Oblique Lumbar Fusion System (K150135 - S.E. 06/11/2015)
- Additional Predicates
- CLYDESDALE® Spinal System K151128 (S.E. 08/06/2015)
  - CLYDESDALE® Spinal System K133577 (S.E. 09/26/2014)

- PERIMETER® Interbody Fusion Device  
K131669 (S.E. 11/01/2013)
- PYRAMID® +4 Anterior Lumbar Plate System  
K071416 (S.E. 11/01/2007)
- ZPLATE II™ Anterior Fixation System  
K991460 (S.E. 05/19/1999).
- CD HORIZON® Spinal System  
K091442 (S.E. 07/15/2009)

### **III. Product Description**

The PIVOX™ Oblique Lateral Spinal System consists of interbody cages, plates, and bone screws.

The PIVOX™ Oblique Lateral Spinal System 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 or allograft 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 PIVOX™ Oblique Lateral Spinal System plates and bone screws are available in a broad range of sizes intended for anterior column 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, lateral, or oblique approach. The PIVOX™ Oblique Lateral Spinal System 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.

#### **IV. Indications for Use:**

The PIVOX™ Oblique Lateral Spinal System Interbody Cage is designed to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The PIVOX™ Oblique Lateral Spinal System interbody cage is used for patients diagnosed with DDD at one or two contiguous levels from L2 to S1. 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 PIVOX® Oblique Lateral Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach.

The PIVOX™ Oblique Lateral Spinal System plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral levels, anterior below the bifurcation (L5-S1) of the vascular structures, and oblique or lateral above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be 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 PIVOX™ Oblique Lateral Spinal System components can be used to treat 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.

#### **V. Comparison of Technological Characteristics**

The primary predicate for the PIVOX™ Oblique Lateral Spinal System is the CLYDESDALE® Spinal System (K151128, S.E. 08/06/2015)

The subject PIVOX™ Oblique Lateral Spinal System interbody cages have the same or similar indications, intended use, fundamental scientific technology, and similar materials as the following FDA cleared predicates K151128 (S.E. 08/06/2015) and K131669 (S.E. 11/01/2013).

The subject PIVOX™ Oblique Lateral Spinal System 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), K991460 (S.E. 05/19/1999), K091442 (S.E. 07/15/2009), and K150135 (S.E. 06/11/2015).

## **VI. Performance Data**

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

### Biocompatibility

The biocompatibility evaluation for the subject PIVOX™ Oblique Lateral Spinal 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, no new biocompatibility testing was 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, no new biocompatibility testing was 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 no new biocompatibility testing was required.

#### Mechanical Testing

In accordance with the *Guidance for Industry and FDA Staff - Spinal System 510(k)'s*, and the *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*. 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:

For the Interbody Cages

- Static Compression
- Static Compression Shear
- Compression Fatigue
- Compression-Shear Fatigue
- Subsidence
- Expulsion

For the Plates and Screws

- Construct Static Compression
- Construct Compression Fatigue
- Construct Static Torsion
- Static Push-Out

The subject devices with pre-determined acceptance criteria met the acceptance criteria for all tests.

## **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.