



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

Alphatec Spine, Incorporated
Ms. Renée L. Murphy
Senior Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

August 24, 2016

Re: K160646

Trade/Device Name: XYcor[®] Expandable Spinal Spacer System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: MAX, MQP

Dated: July 25, 2016

Received: July 26, 2016

Dear Ms. Murphy:

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,

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)

K160646

Device Name

XYcor® Expandable Spinal Spacer System

Indications for Use (Describe)

When used as an Intervertebral Body Fusion device, the XYcor Expandable Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The XYcor Expandable Spinal Spacer System is intended for use with autograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

When used as a Vertebral Body Replacement device, the XYcor Expandable Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable partial or total vertebral body due to tumor or trauma (i.e. fracture). VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The XYcor Expandable Spinal Spacer System is intended for use with autograft and/or allograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

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

Device Trade Name: XYcor[®] Expandable Spinal Spacer System

Manufacturer: Alphatec Spine, Inc., 5818 El Camino Real Carlsbad, CA 92008 USA

Contact: Ms. Renée L. Murphy
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Date Prepared: July 27, 2016

Classification: 21 CFR §888.3080, Intervertebral body fusion device
21 CFR §888.3060, Spinal intervertebral body fixation device

Class: II

Product Codes: MAX, MQP

Primary Predicate Device: Alphatec Spine Novel Spinal Spacer System (K080699)

Additional Predicates: Vertebraion XYcor Spinal Implant (K082466)
Globus Medical LATIS Spacers (K123913)

Indications for Use:

When used as an Intervertebral Body Fusion device, the XYcor Expandable Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The XYcor Expandable Spinal Spacer System is intended for use with autograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

When used as a Vertebral Body Replacement device, the XYcor Expandable Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable partial or total vertebral body due to tumor or trauma (i.e. fracture). VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The XYcor Expandable Spinal Spacer System is intended for use with autograft and/or allograft and with supplemental spinal fixation systems and that have been cleared by the FDA.

Device Description:

The XYcor Expandable Spinal Spacer System is an intervertebral body fixation system and vertebral body replacement consisting of implants with various widths, heights, and lordosis to accommodate individual patient pathology. The devices are intended to deploy using Alphatec Spine instruments once placed into the spinal interbody space. System implants and instruments are manufactured from implant grade titanium (Ti-6Al-4V ELI per ASTM F136) and surgical grade stainless steel and silicone rubber respectively. These implants are intended for use with supplemental spinal fixation and bone graft.

Comparison to Predicate Device:

The subject XYcor Expandable Spinal Spacer System is substantially equivalent to the predicate Alphatec Spine Novel Spinal Spacer System (K080699), XYcor Spinal System (K082644), and the Globus Medical LATIS Spacers (K123913) with respect to technological characteristics of indications, design, materials, function, and performance.

Substantial Equivalence:

The subject XYcor Expandable Spinal Spacer System and the cited predicates are similar in design, material, and indications for use. An animal study was performed to evaluate fusion in a sheep model. A cadaver study was performed to validate the surgical technique and implantation of this device for the interbody cage indications. Mechanical testing was performed to demonstrate acceptable performance characteristics and substantial equivalence.

ASTM F2077: Static Axial Compression, Static Compressive Shear, Static Torsion, Cyclical Axial Compression, Cyclical Compressive Shear, Cyclical Torsion Testing
ASTM F266, Static Subsidence

ASTM Draft Standard F-04.25.02.02, Static Expulsion
Lateral and Flexion Extension Bending Subsidence

Conclusion:

The Alphatec Spine XYcor Expandable Spinal Spacer System includes implant and instrument design modifications and the indications for use have been expanded to include lumbar interbody fusion. The 510(k) demonstrates substantial equivalence to predicate devices.