Alphatec Spine

510(k) SUMMARY
March 2011

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008 USA
Direct: (760) 494-6739
Fax: (760) 431-0289

Contact Person: Karla Schaffner, Regulatory Affairs Submission Specialist

Trade/Proprietary Name: Solus Anterior Lumbar Interbody Fusion (ALIF) System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device

Classification Number(s): 21 CFR 888.3080

Product Code(s): MAX

Product Description:

The Solus Anterior Lumbar Interbody Fusion (ALIF) System is an intervertebral body fusion system for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Solus System consists of implants with various sizes and heights available in 7° or 12° lordosis to accommodate individual patient pathology. The implants are manufactured from polyetheretherkeytone (PEEK Optima LT1) material conforming to ASTM F2026 and tantalum radiographic markers (ASTM F560) with internal anchoring blades of titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136.

Indications for Use:

The Solus Anterior Lumbar Interbody Fusion (ALIF) System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin 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 Solus implant is intended to be used with autograft. The device is intended for use with supplemental fixation that is in addition to the integrated blades.

Substantial Equivalence:

The Solus Anterior Lumbar Interbody Fusion (ALIF) System is substantially equivalent to the following predicate devices:

System	Clearance	Date
Incite Innovations Fusions Device	K093808	March 24,2010
LDR ROI-A	K080572	June 25, 2009
Synthes Spine SynFix LR Spacer	K072253	October 12, 2007
Novel Anterior Lumbar Interbody Fusion (ALIF) System	K090782	April 22, 2009

Data was provided which demonstrated the Solus Anterior Lumbar Interbody Fusion (ALIF) System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, intended use, design, material, and function.

Performance Data:

Testing was performed per ASTM 2077-03 for axial compression, dynamic compression, static compression-shear, static torsion, and dynamic torsion testing of intervertebral fusion devices. Testing was performed per ASTM 2267 for subsidence testing of intervertebral fusion devices. Testing was performed per the draft standard ASTM F-04.25.02.02 for static push-out testing. Cadaveric fatigue testing was performed in Flexion-Extension, Lateral Bending and Axial Rotation. Finite element analysis was performed to evaluate the blade /vertebral body interface. The test results demonstrate that the mechanical performance of the Solus Anterior Lumbar Interbody Fusion (ALIF) System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 12 2011

Alphatec Spine, Inc.
% Ms. Karla Schaffner
Regulatory Affairs Submissions Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K102402
Trade/Device Name: Solus Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 18, 2011
Received: March 21, 2011

Dear Ms. Schaffner:

This letter corrects our substantially equivalent letter of March 30, 2011.

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 (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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K102402

Device Name: Solus Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

The Solus Anterior Lumbar Interbody Fusion (ALIF) System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin 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 Solus implant is intended to be used with autograft. The device is intended for use with supplemental fixation that is in addition to the integrated blades.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102402