MAR 0 5 2013

510(k) Summary
Alphatec SOLUS® Anterior Lumbar Interbody Fusion System
510(k) Summary
Date Prepared: December 21, 2012

I	**Company:**	Alphatec Spine, Inc. 5818 El Camino Real Carlsbad, CA 92008. USA
II.	**Contact:**	Trevor J. Denbo Regulatory Affairs Specialist Telephone: 760-494-6951 Fax: 760-431-0289
III.	**Product Name:**	SOLUS® Anterior Lumbar Interbody Fusion (ALIF) System
IV.	**Common Name:**	Intervertebral Fusion Device
V.	**Regulation Number:**	21 CFR 888.3080
VI.	**Classification Product Code:**	OVD
VII.	**Device Equivalence:**	SOLUS® Anterior Lumbar Interbody Fusion (ALIF) Spinal Spacer System - K102402 S.E. 03/30/2011.

VIII. Description:

The Alphatec Solus® Anterior Lumbar Interbody Fusion (ALIF) System is an intervertebral body fixation system consisting of implants with various heights and lordosis to accommodate individual patient pathology. System implants are manufactured from implant grade polyetheretherketone (PEEK), titanium anchoring blades and tantalum radiographic markers. System instruments are manufactured from stainless steel. The Alphatec Solus implant is intended for use with supplemental spinal fixation. Specifically, the Alphatec Solus implant is to be used with the Alphatec's Zodiac® Spinal Fixation System, Aspida™ Anterior Lumbar Plating System, ILLICO® MIS Posterior Fixation System, ILLICO® FS Facet Fixation System, or the BridgePoint™ Spinous Process Fixation System.

IX. Indications for Use:

The Alphatec 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 to S1. These DDD Patients may also have 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 Alphatec 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.

X. Summary of the Technological Characteristics:

The design, materials, and indications for use of the subject Alphatec Solus® Anterior Lumbar Interbody Fusion (ALIF) System are substantially equivalent to the previously cleared predicate Solus® Anterior Lumbar Interbody Fusion System (K102402). Both system implants are comprised of a PEEK cage surrounding two internal fixation anchor blades which are separated by a C-Ring.

XI. Discussion of the Non-clinical Testing:

Static Axial Compression, Dynamic Axial Compression, Compression Shear Testing, Static Torsion and Dynamic Torsion tests were conducted per ASTM F2077; Subsidence Testing was conducted per ASTM F2267 and Static Expulsion testing was conducted per ASTM Draft Standard F-04.25.02.02. ASTM F2077 and ASTM F2267 standards are Recognized Consensus Standards associated with the OVD product code per the FDA Product Classification.

XII. Non-clinical Testing Conclusions:

All testing passed established acceptance criteria. Based on the results of these tests the Alphatec Solus® Anterior Lumbar Interbody Fusion (ALIF) System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 5, 2013

Alphatec Spine, Incorporated
% Mr. Trevor Denbo
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K123993
Trade/Device Name: Alphatec 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: December 21, 2012
Received: December 26, 2012

Dear Mr. Denbo:

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 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 Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123993

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

Indications For Use:

The Alphatec 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 to S1. These DDD Patients may also have 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 Alphatec 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices