



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

Spine Innovation, LLC  
% Mr. Jude Paganelli  
Cor Medical Ventures, LLC  
215 South Highway 101, Suite 200  
Solana Beach, California 92075

January 14, 2016

Re: K153356  
Trade/Device Name: Spine Innovation Interbody System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: November 19, 2015  
Received: November 20, 2015

Dear Mr. Paganelli:

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 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)

K153356

K153356

Page 1 of 1

Device Name

Spine Innovation Interbody System

### Indications for Use (Describe)

The Spine Innovation Interbody System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The Spine Innovation Interbody System is intended for use with autograft and is intended for use with supplemental fixation. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the Spine Innovation Interbody System.

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

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**SUBMITTER:** Spine Innovation LLC  
215 S. Highway 101, Suite 200  
Solana Beach, CA 92075  
858-774-7891

**CONTACT PERSON:** Jude Paganelli

**DATE PREPARED:** November 19, 2015

**TRADE NAME:** Spine Innovation Interbody System

**COMMON NAME:** Intervertebral Body Fusion Device

**CLASSIFICATION NAME:** Intervertebral Body Fusion Device (21 CFR 888.3080)

**PRODUCT CODE:** MAX

## **SUBSTANTIAL EQUIVALENCE:**

The Spine Innovation Interbody System is substantially equivalent to the competitive devices in all facets including: function, design, performance, material, and intended use.

Primary Predicate Device: Globus Medical LATIS™ Spacers (K123913)

Additional Predicate Devices: Eisertech PLIF Cage (K113478)  
Synthes OPAL Spacer (K072791)  
Alphatec Epicage (K130548)  
SeaSpine Pacifica™ (K082310)

No reference devices were used in this submission.

## **DEVICE DESCRIPTION:**

The Spine Innovation Interbody System is an interbody fusion device and corresponding instruments intended to stabilize the spinal segment to promote fusion. The Spine Innovation Interbody consists of PEEK walls, an autogenous material aperture, two titanium linkages that connect the PEEK walls, angular anti-migration teeth, and tantalum x-ray markers.

The Spine Innovation Interbody is available in various sizes to accommodate varying patient anatomy. The Spine Innovation Interbody is available in undeployed widths ranging from 8-12mm, heights ranging from 8-16mm, lengths of 26 or 30mm, and lordotic angles of 0° (parallel), 5°, 10° or 15°.

The Spine Innovation Interbody System implants are intended to be inserted posteriorly via an open or minimally invasive approach.

The Spine Innovation Interbody System is non-sterile and is to be sterilized by the end user.

## **MATERIALS:**

The Spine Innovation Interbody is manufactured from polyetheretherketone (PEEK) per ASTM F2026 and contains titanium alloys (Ti-6Al-4V per ASTM F1472 and Ti-6Al-4V ELI per ASTM F136) and tantalum per ASTM F560.

## **INDICATIONS FOR USE:**

The Spine Innovation Interbody System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The Spine Innovation Interbody System is intended for use with autograft and is intended for use with supplemental fixation. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the Spine Innovation Interbody System.

## **SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:**

The Spine Innovation Interbody System is substantially equivalent to the predicate devices in all facets including: function, design, performance, material, and intended use. This conclusion is supported by substantially equivalent results of non-clinical testing (listed below).

## **PERFORMANCE TESTING:**

Spine Innovation conducted the following bench tests:

- Static and Dynamic Axial Compression per ASTM F2077
- Static and Dynamic Shear Compression per ASTM F2077, and a Custom Static Shear Compression Test
- Subsidence per ASTM F2267
- Expulsion per ASTM Draft Standard F04.25.02.02

Additional cadaveric testing has been performed to validate the surgical technique.

In summary, mechanical testing of the Spine Innovation Interbody indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

## **CONCLUSIONS:**

The Spine Innovation Interbody System has shown to be substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing and comparison to predicate devices.