



Food and Drug Administration
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Pinnacle Spine Group, LLC
Ms. Rebecca K. Pine
Consultant
1601 Elm Street, Suite 1930
Dallas, Texas 75201

November 19, 2015

Re: K152259
Trade/Device Name: InFill® Interbody Fusion Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 19, 2015
Received: October 20, 2015

Dear Ms. Pine:

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)

K152259

Device Name

InFill® Interbody Fusion Devices

Indications for Use (Describe)

InFill® interbody fusion device is indicated for intervertebral body fusion of the spine in skeletally mature patients. InFill® interbody fusion device is designed for use with autogenous bone graft to facilitate fusion. InFill® interbody fusion device is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. InFill® interbody fusion device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and transforaminal.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Pinnacle Spine Group, LLC

DATE PREPARED: November 17, 2015

CONTACT PERSON: Rebecca K Pine
1601 Elm Street, Suite 1930
Dallas, TX 75201
Phone: 760.809.5178
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TRADE NAME: InFill® Interbody Fusion Device

COMMON NAME: Spinal Implant

CLASSIFICATION NAME: Intervertebral Body Fusion Device

DEVICE CLASSIFICATION: Class 2, per 21 CFR 888.3080

PRODUCT CODE MAX

PREDICATE DEVICES: (primary) InFill® Interbody Fusion Device (K151184)

Substantially Equivalent To:

The InFill® V2 Lateral is a modified device of the existing InFill Interbody Fusion Device product family. The InFill® V2 Lateral is substantially equivalent in intended use, principal of operation and technological characteristics to the InFill® Interbody Fusion Device cleared under premarket notification K151184.

Description of the Device Subject to Premarket Notification:

The InFill® V2 Lateral is a radiolucent implantable device manufactured from PEEK and tantalum (marker material). The implant is available in various sizes to suit the individual pathology and anatomical conditions of the patient.

The InFill® V2 Lateral is provided sterile, for single use only.

Indication for Use:

InFill® interbody fusion device is indicated for intervertebral body fusion of the spine in skeletally mature patients. InFill® interbody fusion device is designed for use with autogenous bone graft to facilitate fusion. InFill® interbody fusion device is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the

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treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. InFill® interbody fusion device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and transforaminal.

Technical Characteristics:

The InFill® V2 Lateral has similar physical and technical characteristics to the predicate device. Additional sizes has been added to the product family and minor design changes have been incorporated as shown in the table below.

Technical Characteristics	InFill® interbody fusion device	InFill® interbody fusion device (K51184)
Shape	Oval-shaped, bullet nose	Oval-shaped, bullet nose
Bone to implant surface	Surface teeth	Surface teeth
Bone graft support feature	SAME	Central fenestration
Primary implant material	SAME	PEEK OPTIMA LT1 ®
Surgical Approach	SAME	Lateral
Lengths (mm)	30-60	25-60
Widths (mm)	18, 21, 24	10-39
Heights (mm)	SAME	8-14
Marker diameter	1.0mm	1.5mm
Surface geometry	SAME	Flat Convex Contoured

Performance Data:

An FEA (Finite Element Analysis) was performed to assess the introduction of the new InFill® V2 Lateral into the existing product family. The worst case construct was identified and characterized. Testing modalities investigated included axial compression and static subsidence. Fatigue failure was also analyzed. The results of the analysis demonstrated that no new mechanical testing is required as the InFill V2 Lateral showed lower principle stresses compared to the predicate device. The analysis demonstrated the substantial equivalence of the new device to the predicate device. The InFill® V2 Lateral device met all specified criteria and did not raise new safety or performance questions.

510(k) Summary

Basis for Determination of Substantial Equivalence:

The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The InFill® V2 Lateral is found to have a safety and effectiveness profile that is similar to the predicate device and is determined by Pinnacle Spine Group LLC, to be substantially equivalent to the predicate devices.