December 14, 2017

Pinnacle Spine Group, LLC
% Mr. Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K172349
Trade/Device Name: InFill® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 13, 2017
Received: November 15, 2017

Dear Mr. Maxwell:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K172349

Device Name
InFill® Interbody Fusion Device

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 and lateral.

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.
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.
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510(K) SUMMARY

Submitter's Name:	Pinnacle Spine Group, LLC
Submitter's Address:	2921 Canton St. Dallas TX, 75226
Submitter's Telephone:	214.466.1428
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874 kmaxwell@empiricalconsulting.com
Date Summary was Prepared:	13 November 2017
Trade or Proprietary Name:	InFill® Interbody Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080 Device Classification
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The InFill® Interbody Fusion Device product family consists of radiolucent implantable devices manufactured from PEEK-OPTIMA® LT1 or PEEK-OPTIMA® HA Enhanced and contains tantalum (marker material). The implants are available in various sizes to suit the individual pathology and anatomical conditions of the patient. The InFill® Interbody Fusion Device is provided sterile.

INDICATIONS 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 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 and lateral.

TECHNOLOGICAL CHARACTERISTICS

The InFill® V2 Lateral Device and InFill Anatomic ALIF are made from material that conforms to ASTM standards. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for use
- Implants Materials
- Structural support mechanism
- Principles of operation

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K152259	InFill® V2 Lateral	Pinnacle Spine Group	Primary
K150206	InFill® Interbody Fusion Device	Pinnacle Spine Group	Additional
K133721	InFill® Interbody Fusion Device	Pinnacle Spine Group	Additional
K150321	EVOS Lumbar Interbody System	Cutting Edge Spine	Additional

PERFORMANCE DATA

The InFill® V2 Lateral Device (worst case device) has been tested in the following test modes:

- Static axial compression per ASTM F2077-14
- Static subsidence per ASTM F2267-04
- Static expulsion per ASTM F-04.25.02.02
- Dynamic axial compression per ASTM F2077-14

The results of this non-clinical testing show that the strength of the InFill® V2 Lateral Device is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the InFill® Interbody Fusion Device is substantially equivalent to the predicate device.