MAY 0 5 2014

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:	May 1, 2014
CONTACT PERSON:	Rebecca K Pine 1601 Elm Street, Suite 1930 Dallas, TX 75201 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	InFill® Cervical
COMMON NAME:	Spinal Implant
CLASSIFICATION NAME:	Intervertebral Body Fusion Device
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	888.3080 (product code: ODP)
PREDICATE DEVICES:	Calix- Cervical Spinal Implant System (K083637, K112036) Bengal Cervical System (K081917)

Substantially Equivalent To:

The InFill® Cervical Interbody Fusion device are substantially equivalent in intended use, principal of operation and technological characteristics to the Calix Cervical Spinal Implant System and the Bengal Cervical System.

Description of the Device Subject to Premarket Notification:

The InFill® Cervical Interbody Fusion device are radiolucent implantable devices manufactured from PEEK Optima LT1 and tantalum ASTM F560 (marker material). The implants are available in various sizes to suit the individual pathology and anatomical conditions of the patient.

The InFill® Cervical Interbody Fusion device is provided sterile, for single use only.

Indication for Use:

InFill® cervical interbody fusion device is indicated for intervertebral body fusion of the spine in skeletally mature patients. InFill® cervical interbody fusion device is designed

for use with autogenous bone graft to facilitate fusion. InFill® is intended for use at one level in the cervical spine, from C2-T1, for the treatment of degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The devices are to be used in patients who have had at least six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with this device. InFill® cervical interbody fusion device is intended to be used with supplemental internal fixation systems that are cleared by the FDA for use in the cervical spine.

Technical Characteristics:

The InFill® 41-TLIF Convex Oblique device, InFill® 43-TLIF Contour Oblique, InFill® 44-TLIF Contour Oblique and the InFill® 60-ALIF have similar physical and technical characteristics to the predicate devices, as illustrated in the table below.

Technical Characteristics	InFill® cervical intervertebral body fusion devices	Calix Cervical Spinal Implant System (K083637, K112036)	Bengal Cervical System (K081917)
Shape	Box-shaped, bullet nose	SAME	SAME
Bone to implant surface	Surface teeth	SAME	SAME
Bone graft support feature	Central fenestration	SAME	SAME
Primary implant material	PEEK OPTIMA LT1 ®	SAME	Carbon fiber reinforced polymer (PEEK)
Surgical Approach	Anterior	Anterior	Anterior

Performance Data:

To establish substantial equivalence with predicate devices, testing was performed including static/dynamic axial compression, static/dynamic torsion, subsidence and expulsion. All performance test values met the established acceptance criteria..

Basis for Determination of Substantial Equivalence:

Upon reviewing the performance data provided in this submission and comparing intended use, design, materials, principle of operation and overall technological characteristics, the InFill® Cervical Interbody Fusion devices are determined by Pinnacle Spine Group, LLC, to be substantially equivalent to existing legally marketed devices.

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

May 5, 2014

Pinnacle Spine Group, LLC
% Ms. Rebecca K. Pine
Consultant
1601 Elm Street, Suite 1930
Dallas, Texas 75201

Re: K140066
Trade/Device Name: InFill® Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 3, 2014
Received: April 4, 2014

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 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,

Ronald P. Jean -S for

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 below.

510(k) Number *(if known)*
K140066

Device Name
InFill® Cervical Interbody Fusion Device

Indications for Use *(Describe)*
The InFill® cervical interbody fusion device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The InFill® cervical interbody fusion device is designed for use with autogenous bone graft to facilitate fusion. InFill® is intended for use at one level in the cervical spine, from C2 to T1, for the treatment of degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The devices are to be used in patients who have had at least six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with this device. The InFill® cervical interbody fusion device is intended to be used with supplemental internal fixation systems that are cleared by the FDA for use in the cervical spine.

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)*

James P. Bertram -S
2014.05.05 15:28:35 -04'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."