JUL 14 2014

510(k) Summary

PFX™ Posterior Spinous Fixation System

Date Prepared: July 8, 2014

Company:
Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact:
Marshall C. McCarty
Phone: (801) 261-2236
mmccarty@innovasis.com

Trade Name: PFX™ Posterior Spinous Fixation System

Common Name: Posterior Spinous Fusion Device

Classification:
Regulation No.: 21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis
Class II
Product Code: PEK
Review Panel: Orthopedic/87
Posterior Spine Devices Branch (PSDB)

Substantially Equivalent Device:

K032037, K123246	CD HORIZON® SPIRE™ Z Spinal System
K090252	Aspen™ Spinous Process Fixation System
K133052	Affix Spinous Process Plate System

Device Description: The Innovasis® *PFX™ Posterior Spinous Fixation System* consists of plates, struts and screws that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The components are available in a range of sizes to fit the anatomical needs of a variety of patients. *PFX™* implants are composed of titanium alloy (per ASTM F136).

Performance Data:

Applicable Standards:

- ASTM F1798-97(Reapproved 2008) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- ASTM F1717-12 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

Tests:
Axial Pushoff
Lock Post Dissociation
Torque to Failure
Static Compression Bending
Static Torsion
Dynamic Compression Bending

Testing demonstrates substantial equivalence to the predicates.

Indications for Use: The Innovasis *PFX™ Posterior Spinous Fixation System* is a posterior, non-pedicle supplemental fixation device intended for use in the posterior non-cervical spine (T1-S1) of skeletally mature patients. It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion. The *PFX Posterior Spinous Fixation System* is intended for use at one level, with bone graft material. The *PFX Posterior Spinous Fixation System* is indicated for use as an aid in immobilization and stabilization of spinal segments as an adjunct to fusion for treatment of the following conditions:

- Degenerative disc disease: Back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Trauma: fracture or dislocation
- Spondylolisthesis
- Tumor

Basis for Substantial Equivalence:

The *PFX Posterior Spinous Fixation* device when tested using recognized standardized testing performed comparably to the predicates in all modes of loading and also exceeded the *in vivo* force tolerances of the human spine.

The materials utilized (titanium alloy) are substantially equivalent to the predicates.

The mode of operation (clamping mechanism utilizing wings and spikes, center post and set screw) is substantially equivalent to the predicates.

The indications for use are substantially equivalent.

Summary of Safety And Effectiveness: The *PFX* when used as posterior supplemental fixation to a fusion site is substantially equivalent to the identified predicate 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

July 14, 2014

Innovasis, Incorporated
Mr. Marshall C. McCarty
Director, QA/RA
614 East 3900 South
Salt Lake City, Utah 84107

Re: K132765
Trade/Device Name: PFX™ Posterior Spinous Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 16, 2014
Received: June 17, 2014

Dear Mr. McCarty:

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)*
K132765

Device Name
PFX™ Posterior Spinous Fixation System

Indications for Use *(Describe)*
The Innovasis PFX™ Posterior Spinous Fixation System is a posterior, non-pedicle supplemental fixation device intended for use in the posterior non-cervical spine (T1-S1) of skeletally mature patients. It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion. The PFX Posterior Spinous Fixation System is intended for use at one level, with bone graft material. The PFX Posterior Spinous Fixation System is indicated for use as an aid in immobilization and stabilization of spinal segments as an adjunct to fusion for treatment of the following conditions:

- Degenerative disc disease: Back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Trauma: fracture or dislocation
- Spondylolisthesis
- Tumor

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)*

Zane W. Wyatt
Division of Orthopedic Devices

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."