



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

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

October 14, 2015

Re: K151785  
Trade/Device Name: Px HA™ PEEK IBF System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: September 1, 2015  
Received: September 2, 2015

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,

**Mark N. Melkerson -S**

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

Enclosure

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		June 26, 2015

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#### 4.0 Indications for Use Statement

510(k) Number: K151785

Device Name: Px HA™ PEEK IBF System

**INDICATIONS FOR USE** are as follows:

##### **Indications for Use:**

The Innovasis *Px HA™ PEEK IBF System* is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior (PLIF) or modified transforaminal (T-PLIF) approach.

This device is intended to be used in pairs and with internal supplemental spinal fixation systems such as the Innovasis *Excella® Spinal System*. The interior of the *Px HA* implant is intended to be packed with autograft.

Prescription Use     **X**      
(21 CFR 801 Subpart D)

OR Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

\_\_\_\_\_  
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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## 5.0 510(k) Summary Report:

### *Px HA™ PEEK IBF System*

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

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

**Trade Name:** Px HA™ PEEK IBF System

**Common Name:** Intervertebral fusion device with bone graft

**Classification:** Regulation No.: 21CFR 888.3080  
Class 2  
Product Code: MAX  
Review Panel: Orthopedic ASDB  
Applicable Standards:

- ASTM F560-13 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopedic Implant Components
- ASTM F2026-14 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F2077-11 Test Methods for Intervertebral Body Fusion Devices
- ASTM F2267-04 (Reapproved 2011) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- ISO 17665-1: 2006 (Reapproved 2013) Sterilization of Healthcare Products – Moist Heat – Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

**Predicate Device:** K150500 Innovasis Px™ PEEK IBF System  
This predicate has not been subject to a design-related recall.

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**Reference Devices:** P960025 Jaguar IF / Brantigan Cage  
K073177 Pioneer Bullet Tip IBF

**Device Description:** The Innovasis *Px HA™ PEEK IBF* is designed for use in a posterior (PLIF) approach to the lumbar spine. Implants are manufactured by Innovasis from Invibio® *PEEK-OPTIMA® HA Enhanced\**. Hydroxyapatite (HA) is fully integrated into the PEEK-OPTIMA. The device is radiolucent allowing straightforward assessment of the fusion process, while tantalum spheres are located around the periphery of the device to allow implant visualization during and after surgery.

The single use implant devices feature an open cavity in the interior geometry to accommodate bone graft and maximize bone in-growth, with anti-migration teeth to engage the vertebral endplates and prevent expulsion. The implants have a slightly convex profile and are offered in a variety of different sizes to fit the anatomical needs of a wide variety of patients. The implant has a tapered leading edge which aids in implant insertion due to limited anatomical space. Reusable instruments to support the PLIF surgery are provided with the implants in custom sterilization trays.

**Performance Data:** (Non-clinical)—Performance testing per ASTM F2077-11 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Subsidence and Expulsion indicates that the *Px HA PEEK IBF* is capable of performing in accordance with its intended use. Testing included simulated aging performed on *Px HA PEEK IBF* Devices, which then were subjected to additional dynamic compression and torsion tests in accordance with ASTM 2077.

**Materials:** The implants are machined from Invibio *PEEK-OPTIMA® HA Enhanced\** polyetheretherketone with hydroxyapatite. The radiographic markers meet ASTM F560 for unalloyed Tantalum. The difference in the material vs. the predicate material is hydroxyapatite filled polyetheretherketone (HA PEEK). HA is a naturally occurring mineral in bone and is widely used in the orthopedic field.

\*Invibio and PEEK-OPTIMA® are registered trademarks of Invibio Limited. All rights reserved.

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**Intended Use:** The Innovasis *Px HA PEEK IBF System* is an intervertebral body fusion device intended to stabilize a spinal segment to promote fusion using bone graft, in order to restrict motion and decrease pain.

Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

**Indications for Use:** The Innovasis *Px HA™ PEEK IBF System* is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior (PLIF) or modified transforaminal (T-PLIF) approach.

This device is intended to be used in pairs and with internal supplemental spinal fixation systems such as the Innovasis *Excella® Spinal System*. The interior of the *Px HA* implant is intended to be packed with autograft.

**Basis for Substantial Equivalence:**

The *Px HA PEEK IBF System* has been subjected to risk analysis, engineering analysis and testing to recognized standards on new and artificially aged devices and has been shown to be substantially equivalent to the predicate device, K150500 Innovasis *Px PEEK IBF System*.

The technological characteristics were found to be substantially equivalent in terms of design, sizes, materials (biocompatibility profile and processing), and mechanical strength.

**Conclusion:** The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and as effective, and performs as well as or better than the legally marketed predicate device.