April 17, 2018

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

Re: K180078
Trade/Device Name: Px® PEEK IBF System, Px HA® PEEK IBF System, TxHA™ PEEK IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 16, 2018
Received: March 19, 2018

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.

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
2018.04.17 14:12:14 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180078

Device Name
Px® PEEK IBF System, Px HA® PEEK IBF System, TxHA™ PEEK IBF System

Indications for Use *(Describe)*
The Innovasis PEEK IBF System (Px, Px HA and TxHA) 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. Px® and Px HA® devices are placed via either a posterior (PLIF) or modified transforaminal (T-PLIF) approach. TxHA™ devices are placed via a transforaminal (TLIF) approach.

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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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INNOVASIS INNOVATE / INVOLVE / INVENT	Px®/Px HA®/TxHA™ PEEK IBF	510(k)
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5.0 510(k) Summary Report:

Px®/Px HA®/TxHA™ 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

Trade Name: Px® PEEK IBF System
Px HA® PEEK IBF System
TxHA™ 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 PSDB

Primary Predicate Device: K151785 Innovasis Px HA® PEEK IBF System
This predicate has not been subject to a design-related recall.

Additional Predicates:

K143740	Alphatec Battalion Universal Spacer System
K150500	Innovasis Px PEEK IBF System
K171633	NuVasive TLX Interbody System
K171519	EOI FLXfit™ 15

Device Description:

The *Innovasis TxHA PEEK IBF Spinal System* is a line extension of the *Px Posterior Spinal IBF System,* an intervertebral body fusion device with associated instrumentation for use in Transforaminal Lumbar Interbody Fusion (TLIF) surgeries. The *Px IBF* was submitted to FDA under K150500 in February 2015, and was cleared for sale in the USA on June 19, 2015. The *Px HA* design manufactured using Invibio® *PEEK-Optima® HA Enhanced* was cleared under K151785 on October 14, 2015. In this material, hydroxyapatite (HA), is integrated with Invibio's PEEK-OPTIMA Natural.

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The single use implant devices feature an open cavity in the interior geometry to accommodate bone graft and maximize bone through-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 PLIF/TLIF surgeries are provided with the implants in sterilization trays.

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Performance Data: (Non-clinical)—Performance testing per ASTM F2077-14 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Subsidence and Expulsion indicates that the *Px, Px HA, TxHA PEEK IBF* is capable of performing in accordance with its intended use. Testing included simulated aging performed on *Px HA PEEK IBF* and *TxHA PEEK IBF* Devices, which then were subjected to testing in accordance with ASTM F2077.

Materials: The Px implants are machined from medical grade Solvay Zeniva ZA-500 or Evonik VESTAKEEP i4R PEEK. The *Px HA* and *TxHA* implants are machined from Invibio® *PEEK-OPTIMA® HA Enhanced** polyetheretherketone with hydroxyapatite. The radiographic markers meet ASTM F560 for unalloyed Tantalum. HA is a naturally occurring mineral in bone and is widely used in the orthopedic field.

Intended Use: The Innovasis *PEEK IBF System* (*Px, Px HA* and *TxHA)* 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.

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Indications for Use: The Innovasis *PEEK IBF System* (*Px, Px HA* and *TxHA)* 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. *Px*® and *Px HA*® devices are placed via either a posterior (PLIF) or modified transforaminal (T-PLIF) approach. *TxHA*™ devices are placed via a transforaminal (TLIF) approach.

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

Basis for Substantial Equivalence:

The *Px*/*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 the worst-case size has been demonstrated to be substantially equivalent to the predicate device, K151785 and K150500 when tested singly (not in pairs).

The *TxHA 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, K151785 Innovasis *Px HA 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 substantially equivalent to the legally marketed predicate device.