August 26, 2022

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

Re: K220875
Trade/Device Name: HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 22, 2022
Received: July 25, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220875

Device Name
HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System

Indications for Use *(Describe)*
The Innovasis HAcancellous PEEK-C Porous HA PEEK Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The HAcancellous PEEK-C device is to be used with supplemental fixation, such as the Innovasis Oryx® Cervical Plate System. The HAcancellous PEEK-C device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

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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510(k) Summary Report:

HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System

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

Contact: Marshall C. McCarty
Phone: (801) 261-2236 x8012
mmccarty@innovasis.com

Trade Name: HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System

Common Name: Intervertebral fusion device with bone graft, Cervical

Classification: Regulation No.: 21CFR 888.3080
Class 2
Product Code: ODP
Review Panel: 87 - Orthopedic

Primary Predicate: K181115 Innovasis *CxHA® PEEK Cervical IBF System*
This predicate has not been subject to a design-related recall.

Additional Predicate: K173030 Nuvasive *Cohere Cervical IBF*

Device Description: The *HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System* is for Anterior Cervical Discectomy and Fusion (ACDF). The implant is available in multiple size options to match vertebral anatomy and is intended to stabilize a cervical spinal segment to promote fusion which restricts motion and decreases pain.

The *HAcancellous PEEK-C* Implants are made from Invibio® PEEK-OPTIMA® HA Enhanced[1] and include Pore Matrix™ Technology[2]. Hydroxyapatite (HA) is fully integrated throughout the implant, including the porous layers. The *HAcancellous PEEK-C* Implant is made from PEEK which has a modulus of elasticity similar to human vertebral bone. The Porous Layers on the endplate contact surfaces and along the vertical walls of the graft window utilize Pore Matrix Technology, a geometry that unlike smooth PEEK, is designed to mimic anatomical cancellous bone, with interconnected spherical pores. The surface porosity is designed to promote cell signaling, on-growth, in-growth, and

[1] Invibio® and PEEK-OPTIMA® are registered trademarks of Invibio Limited. All rights reserved.
[2] Pore Matrix Technology by Pore Matrix, LLC. California, USA

fusion. The *HAcancellous PEEK-C* Implant may provide an increased opportunity for bone ingrowth and for achieving early integration[3]. *In vitro performance or animal studies may not be representative of clinical performance.* The *HAcancellous PEEK-C* Implant features a tapered nose to aid in insertion and protect the porous layer during insertion, a graft cavity to provide volume for bone graft, and is radiolucent allowing assessment of the fusion process, while three tantalum spheres enable implant visualization during the surgical procedure. The implants come in 7 heights, 6-12mm in 1mm increments and 8 Footprints with an 8° lordotic angle.

Reusable instruments to support ACDF surgeries are provided with the implants in sterilization sets. Innovasis implants are designed and validated for use with these instruments described in the Surgical Technique Guide. Usage of any instrumentation outside of the validated design intent is considered off-label use.

Performance Data: The mechanical performance and fatigue endurance of the *HAcancellous PEEK-C* implants was conducted in accordance with ASTM F2077, “Test Methods for Intervertebral Body Fusion Devices", ASTM F2267, “Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Devices under Static Axial Compression”. The ASTM F2077 standard is designed for testing intervertebral body fusion devices and is followed to assess the static and dynamic strength and fatigue endurance of the interbody fusion device in compression, compression-shear, and torsional loading paradigms. The device was also evaluated in expulsion and simulated insertion.

The Innovasis *HAcancellous PEEK-C* cervical interbody fusion device exhibited substantially equivalent characteristics to previously cleared predicate devices and FDA published data for strength, stiffness, and cyclic endurance in all planes of spinal loading.

Materials: The *HAcancellous PEEK-C* implants are manufactured from Invibio® *PEEK-OPTIMA® HA Enhanced* polyetheretherketone with hydroxyapatite. HA is a naturally occurring mineral in bone and is

[3] University of New South Wales – Surgical & Orthopaedic Research Laboratories – In-vivo evaluation of osteo integration of PEEK and surface modified PEEK in an ovine model. Note: this study was conducted on standard PEEK, not PEEK-OPTIMA® HA Enhanced from Invibio®. The porous structure for the HAcancellous PEEK-C device has been modified from the one used for this study with the intent to increase pore interconnectivity and optimize pore size for bone in-growth.

widely used in the orthopedic field. The radiographic markers meet ASTM F560 for unalloyed Tantalum.

The *HAcancellous PEEK-C* instruments/accessories are machined from Surgical Stainless Steel per ASTM F899. The *HAcancellous PEEK-C* rasps are coated with Titanium Nitride.

The *HAcancellous PEEK-C* sterilization sets are comprised of Anodized 5052 Aluminum and have components made of Nylon, Silicone, Stainless Steel, and RADEL per ASTM D6394 SP031.

Intended Use: The Innovasis *HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System* is an intervertebral body fusion (IBF) device with associated instrumentation, used with bone graft material. The device is intended to stabilize a cervical 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 *HAcancellous PEEK-C Porous HA PEEK Cervical IBF System* is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.
This device is to be used in patients who have had six weeks of non-operative treatment. The *HAcancellous PEEK-C* device is to be used with supplemental fixation, such as the Innovasis *Oryx®* *Cervical Plate System*. The *HAcancellous PEEK-C* device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

Comparison of Technological Characteristics with the Predicate Devices:
The *HAcancellous PEEK-C Porous HA PEEK Cervical IBF System* has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the predicate devices, K181115, Innovasis *CxHA® PEEK Cervical IBF System* and K173030, Nuvasive *Cohere Cervical IBF*.

- Technology is substantially equivalent.
- Design and implant sizes are substantially equivalent.
- Mechanical strength is substantially equivalent.

- Indications for use are substantially equivalent.
- Materials (biocompatibility profile) are substantially equivalent.

Conclusion: The overall technology characteristics and mechanical performance data lead to the conclusion that the subject device is substantially equivalent to legally marketed predicate devices.