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

July 16, 2018

Re: K181115
Trade/Device Name: CxHA™ PEEK Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: April 27, 2018
Received: April 27, 2018

Dear Marshall 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 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,

Brent Showalter -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181115

Device Name
CxHA™ PEEK Cervical IBF System

Indications for Use *(Describe)*

The Innovasis CxHA 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 CxHA device is to be used with supplemental fixation, such as the Innovasis Opteryx® Cervical Plate System. The CxHA device is intended to be used with autograft 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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5.0 510(k) Summary Report:

CxHA™ PEEK Cervical IBF System

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

Contact: Marshall McCarty
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mmccarty@innovasis.com

Alternate: Michael Thomas
(801) 261-2236 x8002
mthomas@innovasis.com

Trade Name: CxHA™ 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: Orthopedic - ASDB
Applicable Standards:

Primary Predicate: K172674 Sapphire Cervical Implant System (Sapphire Medical)

Additional Predicates:
K122444 Eisertech Cervical Cage (Eisertech, LLC)
K132991 C-Box PEEK Cervical IBF (Innovasis, Inc.)

Device Description: *CxHA PEEK Cervical IBF System*
The *CxHA PEEK Cervical IBF System* is a spinal intervertebral fusion device made from hydroxyapatite infused polyetheretherketone. It is provided in a variety of footprint sizes ranging from 12mm anterior-posterior x 14mm medial-lateral to 16mm anterior-posterior x 19mm medial-lateral. It is provided in heights from 6mm to 12mm in 1mm size increments with 8° lordosis. There is an interior cavity for use with autogenous bone graft material. It has two radiographic marker spheres made from tantalum per ASTM F560.

Performance Data: (Non-clinical)—Performance testing per ASTM F2077-17 for Static Compression, Static Torsion and Dynamic Torsion indicates that

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the *CxHA PEEK Cervical IBF* is substantially equivalent to the predicate device.

Materials: The implants are machined from medical grade polyetherether-ketone infused with hydroxyapatite (Invibio® *PEEK Optima® HA Enhanced).* The radiographic markers meet ASTM F560 for unalloyed Tantalum.

Intended Use: The *CxHA PEEK Cervical IBF* device is intended for use in Anterior Cervical Discectomy and Fusion (ACDF) procedures.

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 *CxHA™ 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 *CxHA* device is to be used with supplemental fixation, such as the Innovasis *Opteryx® Cervical Plate System*. The *CxHA* device is intended to be used with autograft bone and is to be implanted via an anterior approach.

Comparison of the Technological Characteristics with Predicate Device:

The *Innovasis CxHA 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 Sapphire Medical Group *Cervical Cage* (K172674) and the *C-Box PEEK Cervical IBF System* (K132991) predicates.

- Design configurations are substantially equivalent.
- Applied mechanical loads are substantially equivalent.
- Materials used are substantially equivalent.
- Biocompatibility requirements have been demonstrated.
- Manufacturing and processing methods are similar if not identical.
- Shelf life is substantially equivalent.
- Intended Use and Indications for Use are substantially equivalent.

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The design of the predicate K172674 device has been provided to Innovasis by Sapphire Medical Group. The implant dimensions are identical. The instruments are equivalent; Innovasis has added a graft block, bone graft tamp and implant tamp that are not part of the Sapphire system. Three modifications have been made to the implant design when compared to the predicate: The material is Invibio *PEEK OPTIMA HA Enhanced,* the device is provided sterile and the radiographic markers are tantalum spheres instead of tantalum pins.

Conclusion: Performance data and rationales submitted herein demonstrate that the subject *CxHA PEEK Cervical IBF* device is substantially equivalent to the predicate devices with regard to design, technological characteristics, materials, performance, intended use and indications for use.