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

June 17, 2019

Re: K190684
Trade/Device Name: LxHA™ PEEK Lateral IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 21, 2019
Received: May 22, 2019

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. 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,

for Melissa Hall
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190684

Device Name
LxHA™ PEEK Lateral IBF System

Indications for Use *(Describe)*
The Innovasis® LxHA™ PEEK Lateral IBF 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 Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed using a lateral 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 device 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	**LxHA™ PEEK Lateral IBF**	

510(k) Summary:

LxHA™ PEEK Lateral IBF System

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

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

Trade Name: LxHA™ PEEK Lateral IBF System

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

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

Primary Predicate: K121581 Innovasis *Box PEEK IBF System*
This predicate has not been subject to a design-related recall.

Additional Predicate:
K180078 Innovasis *Px HA® PEEK IBF System*

Reference Device:
K170395 Meditech Spine *Talos®-L (HA) Lumbar PEEK Interbody Device*
K133455 Pioneer Surgical Technology (RTI Surgical) *CrossFuse II IBFD* (Labeling Recall Z-1916-2015)

Device Description:

The *LxHA PEEK Lateral IBF System* is Innovasis' next generation intervertebral body fusion device with associated instrumentation for use in Lateral Lumbar Interbody Fusion (LLIF) surgeries. The *L-Box IBF* was initially submitted to FDA under K121581 in September 2012 and was cleared for sale in the USA on October 17, 2012.

The *LxHA* implants will be manufactured using Invibio *PEEK-Optima HA Enhanced*. In this material, hydroxyapatite (HA) is integrated with Invibio's PEEK-OPTIMA Natural. The *LxHA* implants will be manufactured using HA PEEK and are to be sold sterile.

INNOVASIS INNOVATE / INVOLVE / INVENT	LxHA™ PEEK Lateral IBF	

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 are offered in a variety of different sizes to fit the anatomical needs of a wide variety of patients, including 0°, 8°, 12°, and 16° of lordosis. The implant has a tapered leading edge which aids in implant insertion due to limited anatomical space. Reusable instruments to support LLIF surgeries are provided with the implants in sterilization trays.

Performance Data: (Non-clinical)—Performance testing per ASTM F2077-18 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Subsidence and Expulsion indicates that the *LxHA PEEK Lateral IBF* is capable of performing in accordance with its intended use. Testing included simulated aging performed on *LxHA PEEK Lateral IBF* devices, which then were subjected to testing in accordance with ASTM F2077.

The subject *LxHA* device demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.

Materials: The *LxHA* implants are machined from Invibio® *PEEK-OPTIMA®* *HA Enhanced** polyetheretherketone with hydroxyapatite. The radiographic markers meet ASTM F560 for unalloyed Tantalum and ASTM F136 for Ti 6Al 4V ELI respectively. HA is a naturally occurring mineral in bone and is widely used in the orthopedic field.

The LxHA instruments/accessories are machined from Surgical Stainless Steel per ASTM F899 and Titanium 6Al-4V ELI per ASTM F136, and have medical grade Silicone handles.

The LxHA sterilization trays are comprised of Anodized 5052 Aluminum and have components made of Nylon, Stainless Steel, Polypropylene, and RADEL per ASTM D6394 SP031.

Intended Use: The *LxHA PEEK Lateral 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.

INNOVASIS INNOVATE / INVOLVE / INVENT	**LxHA™ PEEK Lateral IBF**	

Indications for Use: The Innovasis® LxHA™ PEEK Lateral IBF 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 Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed using a lateral 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 device is intended to be packed with autograft.

Comparison of Technological Characteristics with the Predicate Devices:

The *LxHA PEEK Lateral 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, K121581 Innovasis *Box PEEK IBF System* and K180078 Innovasis *Px HA® PEEK IBF System.*

- Technology is substantially equivalent.
- Design is substantially equivalent.
- Sizes are substantially equivalent.
- Mechanical strength is substantially equivalent.
- Indications for use are substantially equivalent.
- Bone graft window/cavity is 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.