October 15, 2021

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

Re: K212967
Trade/Device Name: AxTiHA® Stand-Alone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: September 15, 2021
Received: September 16, 2021

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,

Brent L. 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)*

K212967

Device Name
AxTiHA® Stand-Alone ALIF System

Indications for Use *(Describe)*

The Innovasis AxTiHA Stand-Alone ALIF 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 levels(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system such as the Innovasis® Excella® Spinal System. The AxTiHA Stand-Alone interbody implants with a lordotic angle less than 20°, when used with all three internal fixation screws, do not require use of supplemental fixation. The interior of the AxTiHA implant is intended to be packed with autograft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

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	AxTiHA® Locking Clip	Special 510(k)
		September 15, 2021

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

1. Submitted by:

Marshall C. McCarty
Director QA/RA
Innovasis, Inc.
614 E 3900 S
Salt Lake City, Utah 84107
Telephone: (801) 261-2236

2. Device Information

Trade Names: AxTiHA® Stand-Alone ALIF System

Common Names: Intervertebral Fusion Device with Integrated Fixation, Lumbar

Product Code: OVD

Classification Name: Intervertebral body fusion device (21 CFR 888.3080)

Review Panel: 87 – Orthopedic Devices (OHT6) – Spinal Devices Branch (DHT6B)

Regulatory Class: Class II

3. Predicate Devices

Primary Predicate Device:

K201614 Innovasis *AxTiHA® Stand-Alone ALIF System*

4. Indications for Use

AxTiHA Stand-Alone ALIF System

The Innovasis *AxTiHA Stand-Alone ALIF 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 levels(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system such as the Innovasis® Excella® Spinal System. The AxTiHA Stand-Alone interbody implants with a lordotic angle less than 20°, when used with all three internal fixation screws, do not require use of supplemental fixation. The interior of the AxTiHA implant is intended to be packed with autograft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

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5. Device Description

The *AxTiHA Stand-Alone ALIF System* is for Anterior Lumbar Interbody Fusion (ALIF). The IBF implants are an additive manufactured device comprised of Ti-6Al-4V (ELI) per ASTM F3001 and Hydroxyapatite (HA) and are available in multiple size options to facilitate a more precise anatomical fit. The IBF implants have a tapered leading edge which aids in implant insertion due to limited anatomical space, feature a bi-convex profile to match the anatomy, and include anti-migration features to ensure implant stability during the fusion process. The large graft cavity and open geometric Tetracell® Technology structure provide increased volume for autograft loading and bone through-growth. The IBF devices include integrated fixation by way of three converging bone screws and optional screw anti-backout locking clips manufactured from Ti-6Al-4V (ELI) per ASTM F136.

6. Intended Use

The Innovasis *AxTiHA Stand-Alone ALIF 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.

7. Technological Characteristics

The subject locking clip is an optional bone screw anti-backout mechanism machined from Ti-6Al-4V (ELI) and is intended to be connected to the face of the stand-alone ALIF IBF device after implantation.

8. Performance Data

Performance testing has been conducted per ASTM F2077 for Dynamic Axial Compression and Dynamic Compression Shear, as well as verification testing for bone screw pushout to confirm there is no degradation in performance of the predicate device when the subject locking clip is applied.

9. Conclusions

The subject *AxTiHA Stand-Alone ALIF System* with the added optional locking clip has been shown to be substantially equivalent to legally marketed predicate device for its intended use.