March 24, 2025

Innovasis
Mr. Mike Thomas
Director Regulatory Affairs
614 E 3900 S
Salt Lake City, Utah 84107

Re: K250603
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: February 27, 2025
Received: February 28, 2025

Dear Mr. Mike Thomas:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

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

510(k) Number *(if known)*
K250603

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K250603

510(k) Summary

Prepared on: 2025-02-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovasis
Applicant Address	614 E 3900 S Salt Lake City UT 84107 United States
Applicant Contact Telephone	8012612236
Applicant Contact	Mr. Mike Thomas
Applicant Contact Email	mthomas@innovasis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AxTiHA® Stand-Alone ALIF System
Common Name	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification Name	Intervertebral body fusion device
Regulation Number	888.3080
Product Code(s)	OVD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212967	AxTiHA® Stand-Alone ALIF System	OVD
K160605	MectaLIF Anterior Stand-Alone	OVD

Device Description Summary

21 CFR 807.92(a)(4)

The AxTiHA 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. Reusable instruments to support the ALIF surgery are provided with the implants in sterilization trays.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use statement of the subject device is substantially equivalent to the predicate devices (K212967 and K160605).

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has substantially equivalent technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate devices (K212967 and K160605).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Engineering analysis of the subject device indicates that additional verification testing is not required to demonstrate substantial equivalence. Previous evaluations and performance testing (e.g., design verification and validation) performed on the predicate devices apply to the subject devices. Based on the information presented above and within the submission, the subject device is substantially equivalent to the predicate devices regarding indications for use, intended use, design, technology, and performance.