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

June 21, 2019

Re: K182139
Trade/Device Name: AXTi™ Titanium Stand-Alone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: May 22, 2019
Received: May 24, 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)*
K182139

Device Name
AXTi™ Titanium Stand-Alone ALIF System

Indications for Use *(Describe)*
The Innovasis AXTi™ Titanium 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 AXTi™ Titanium 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 AXTi 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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510(k) Summary Report:

AXTi™ Titanium Stand-Alone ALIF System

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

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

Trade Name: AXTi™ Titanium Stand-Alone ALIF System

Common Name: Intervertebral Fusion Device with Integrated Fixation, Lumbar

Classification: Regulation No.: 21CFR 888.3080
Class: 2
Product Code: OVD
Review Panel: Orthopedic Devices (OHT6) : Spine Devices (DHT6B)

Primary Predicate:	K162236	Innovasis® Ax® Stand-Alone ALIF System
Add'l Predicate:	K163269	Titan Spine Endoskeleton® TAS System
	K162496	CoreLink Foundation™ 3D Interbody

Device Description: The Innovasis AXTi™ Titanium Stand-Alone ALIF System features a sterile packaged single use implant and associated reusable instrumentation for preparation of the surgical site and implantation of the device provided. The instruments and fixation screws are provided in storage trays for organization and steam sterilization.

The AXTi Titanium Stand Alone ALIF features all titanium (6Al 4V ELI) implant body and bone screws for fixation. The implant is a stand-alone anterior intervertebral body fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The implant body is provided sterile.

- The interior of the device will be packed with autograft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.
- The device is intended to support restoration of the sagittal balance.

- It is intended to be used with all three internal fixation bone screws and will not require additional supplementary fixation for implants with a lordotic angle less than 20°.
- Implants with a lordotic angle ≥20° are indicated for use with supplementary fixation, such as the Excella® Spinal System.
- It is intended for use with the standard anterior (ALIF) approach

Performance Data: (Non-clinical)—Performance testing per ASTM F2077-14 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Static Compression Shear, Dynamic Compression Shear, Subsidence and Expulsion testing indicates that the *AXTi Titanium Stand-Alone ALIF* is substantially equivalent to the predicates.

Materials:

Implants
- Titanium-6-Aluminum-4-Vanadium ELI (Extra Low Interstitial) Alloy

Instruments
- 465 Stainless Steel per ASTM F899
- 17-4 Stainless Steel per ASTM F899
- Silicone Handles (Tested for biocompatibility)
- Radel Handle per ASTM D6394

Sterilization Trays
- Anodized 5052 Aluminum
- Polypropylene
- Radel

Indications for Use: The Innovasis *AXTi Titanium 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 AXTi Titanium 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 *AXTi* implant is intended to be packed with autograft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

Basis for Substantial Equivalence:

The *AXTi Titanium Stand-Alone ALIF 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 device, K162236 Innovasis *Ax Stand-Alone ALIF System,* additional predicate, K163269 Titan Spine *Endoskeleton TAS System* and reference device K162496 CoreLink *Foundation 3D Interbody.*

The *AXTi* device has the following substantially equivalent properties to the predicate devices including the following features:

- Materials (biocompatibility profile)
- Technology (intervertebral body fusion device)
- Design
- Sizes (including lordosis)
- Bone graft window/cavity
- Mechanical strength (substantially equivalent to predicate device K162236 *Ax)*.
- Indications for use
- Manufacturing (3D printing substantially equivalent to reference device K162496 *Foundation)*

Conclusion: The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate devices.