July 15, 2020

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

Re: K201614
Trade/Device Name: TxTiHA™ IBF System, AxTiHA™ Stand-Alone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: June 12, 2020
Received: June 15, 2020

Dear Mr. 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 Showalter, Ph.D.
Acting 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)*

K201614

Device Name
TxTiHA™ IBF System

Indications for Use *(Describe)*

The Innovasis® TxTiHA™ IBF 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 Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via a transforaminal 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 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.

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

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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)*

K201614

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	TxTiHA™ IBF System AxTiHA™ Stand-Alone ALIF System	Special 510(k) June 12, 2020

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

Device Names: Innovasis® TxTiHA™ IBF System
Innovasis® AxTiHA™ Stand-Alone ALIF System

Common Names:
Intervertebral Fusion Device with Bone Graft (*TxTiHA*)
Intervertebral Fusion Device with Integrated Fixation, Lumbar (*AxTiHA*)

Product Code: MAX (*TxTiHA*); OVD (*AxTiHA*)
Classification Name: Intervertebral body fusion device (21 CFR 888.3080)
Review Panel: 87 – Orthopedic Devices (OHT6)
Regulatory Class: Class II

3. Predicate Devices

Primary Predicate Devices:
K183064 – Innovasis *TxTi™ IBF System*
Add'l Predicate Devices:
K182139 – Innovasis *AXTi™ Titanium Stand-Alone ALIF System*
Reference Devices:
K190025 – Cutting Edge Spine *EVOL® - SI Joint Fusion System*
K170392 – S.I.N *Dental Implant System*
K101225 – Promimic *Dental Implant*

4. Indications for Use

TxTiHA™ IBF System

The Innovasis® TxTiHA™ IBF 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 Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via a transforaminal 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 is intended to be packed with autograft.

INNOVASIS INNOVATE / INVOLVE / INVENT	TxTiHA™ IBF System AxTiHA™ Stand-Alone ALIF System	Special 510(k) June 12, 2020

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.

5. Device Description

TxTiHA™ IBF System

The TxTiHA system is an intervertebral body fusion device with associated instrumentation for use in Transforaminal Lumbar Interbody Fusion (TLIF) surgeries. The implant is an additive manufactured device made from the titanium alloy Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial (Ti-6Al-4V ELI) conforming to the ASTM F3001 specifications and features a Promimic HA^{nano} Surface®.[1] Implants are available in various lengths, widths, heights, and degrees of lordosis to facilitate a more precise anatomical fit. The 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. Implants are supplied sterile. Reusable instruments to support the TLIF surgery are provided with the implants in sterilization trays.

AxTiHA™ Stand-Alone ALIF System

The AxTiHA system is for Anterior Lumbar Interbody Fusion (ALIF). The implants are an additive manufactured device comprised of Ti-6Al-4V ELI per ASTM F3001 and feature a Promimic HA^{nano} Surface. Implants are available in multiple size options to facilitate a more precise anatomical fit. The 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.

6. Intended Use

TxTiHA™ IBF System

The Innovasis *TxTiHA 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.

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[1] HA^{nano} is a registered trademark of Promimic AB, Mölndal Sweden

INNOVASIS INNOVATE / INVOLVE / INVENT	**TxTiHA™ IBF System** **AxTiHA™ Stand-Alone ALIF System**	Special 510(k) June 12, 2020

Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

AxTiHA™ Stand-Alone ALIF System
The Innovasis AxTiHA Titanium 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.

Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

7. Technological Characteristics

Innovasis has leveraged 3D printing techniques to develop Patent-Pending Tetracell™ Technology. Tetracell is a titanium, open-cellular matrix of tetrahedrons providing:

- Large inner volume for graft material.
  - TxTiHA has up to 28% more graft volume than a traditional implant
  - AxTiHA has up to 41% more graft volume than a traditional implant
- Micro-textured surface geometry
- Large endplate contact surface area to distribute compressive loads
- Tetracell™ structure reduces the radiographic signature
- HA^{nano} Surface[2]

8. Performance Data

Performance testing per ASTM F2077-17 and F2267-04 for Static Axial Compression, Dynamic Axial Compression, Static Compression Shear, Dynamic Compression Shear, Subsidence and Expulsion testing performed on the predicates applies to the modified devices because there is no difference in size, dimension, raw material or manufacturing method or equipment with the exception of a nanometer thin layer of hydroxyapatite (a naturally occurring substance in the body in the area of the spine and other bone) applied to the surface.

(Non-clinical)—Performance testing performed per Promimic protocol accepted by FDA for the testing of HA^{nano} Surface integrity for the clearance of the reference devices (K190025, Cutting Edge Spine *EVOL SI Joint Fusion System*) and (K170392, S.I.N *Dental Implant System*).

9. Conclusions

The subject TxTiHA IBF System and AxTiHA Stand-Alone ALIF System have been shown to be substantially equivalent to legally marketed predicate devices for their intended uses.

[2] Promimic AB, Mölndal Sweden