DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 20, 2017

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

Re: K162236
Trade/Device Name: Ax™ Stand-Alone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 8, 2017
Received: March 21, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162236

Device Name
Ax™ Stand-Alone ALIF System

Indications for Use *(Describe)*

The Innovasis Ax 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 Ax Stand-Alone interbody implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of supplemental fixation.

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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4.0 510(k) Summary Report:

Ax™ 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: Ax™ Stand-Alone ALIF System

Common Name: Intervertebral fusion device with bone graft

Classification: Regulation No.: 21CFR 888.3080
Class 2
Product Code: OVD
Review Panel: Division of Orthopedic Devices (DOD) - Anterior Spine Devices Branch (ASDB)

Primary Predicate: K121211 Integra Vu a•POD™ Prime System
(SeaSpine has separated from *Integra* and now owns this product line.) This predicate has not been subject to a design-related recall.

Additional Predicates:
K123045 Nuvasive® Brigade™ Hyperlordotic Implant System
K151785 Innovasis® Px HA™ PEEK IBF System

Device Description: The Innovasis *Ax Stand-Alone ALIF* implant will be provided in two configurations. The first is an HA PEEK cage with an integrated titanium faceplate. The second is an all titanium version of the same implant. Both designs will feature screws, a locking mechanism, and instruments. The implant is a stand-alone anterior intervertebral body fusion device indicated for use in patients with degenerative disk 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 interior of the device will be packed with autograft.
- Intended to support restoration of the sagittal balance.
- It is intended to be used with 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 approach

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

Materials:

Implants

- *Invibio® PEEK-OPTIMA® HA Enhanced Polyetheretherketone with hydroxyapatite for surgical implant
- Unalloyed Tantalum per ASTM F560
- 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 Ax 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 Ax Stand-Alone interbody implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of supplemental fixation.

Basis for Substantial Equivalence:

The *Ax 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, K121211 Integra *Vu a•POD,* and reference devices, K151785 Innovasis Px HA PEEK IBF System and K123045 NuVasive *Brigade HL*.

- Materials (biocompatibility profile and processing) are substantially equivalent to predicate device.
- Technology is substantially equivalent to predicate device.
- Design is substantially equivalent to predicate device.
- Sizes are substantially equivalent to predicate device.
- Bone graft window/cavity is substantially equivalent to predicate device.
- Mechanical strength is substantially equivalent to predicate device.
- Indications for use are substantially equivalent to predicate device.

Conclusion:

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