October 17, 2023

Innovasis, Inc.
Michael Thomas
Director Regulatory Affairs
614 E 3900 South
Salt Lake City, Utah 84107

Re: K231899
Trade/Device Name: HAtetracell™-C Titanium Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 16, 2023
Received: October 16, 2023

Dear Michael 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.

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231899

Device Name

HAtetracell™-C Titanium Cervical IBF System

Indications for Use *(Describe)*

The Innovasis HAtetracell™-C Titanium Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.
This device is to be used in patients who have had six weeks of non-operative treatment. The HAtetracell™-C device is to be used with supplemental fixation, such as the Innovasis Oryx® Cervical Plate System. The HAtetracell™-C device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

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.

510(k) Summary

Prepared on: 2023-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovasis, Inc
Applicant Address	614 E 3900 S Salt Lake City UT 84107 United States
Applicant Contact Telephone	(801) 261-2236
Applicant Contact	Mr. Michael Thomas
Applicant Contact Email	mthomas@innovasis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HAtetracell™-C Titanium Cervical IBF System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code	ODP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220875	HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System	ODP
K201614	TxTiHA™ IBF System	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The HAtetracell™-C Titanium Cervical IBF System is an intervertebral body fusion (IBF) device with associated instrumentation, used with bone graft material, intended to stabilize a cervical spinal segment to promote fusion which restricts motion and decreases pain. The HAtetracell™-C Titanium Cervical IBF System is implanted via an Anterior Cervical Discectomy and Fusion (ACDF) surgical approach. The HAtetracell™-C implants are an additive manufactured device made from titanium alloy Ti-6Al-4V ELI per ASTM F3001 and are coated with a hydroxyapatite HAnano surface. The trabecular structures on the endplate contact surfaces feature porous macro-, micro-, and nanofeatures that are designed to mimic cortical and cancellous bone to help facilitate intervertebral fusion. The HAtetracell™-C implant features a tapered nose to aid in insertion and protect the porous layer during insertion, a graft cavity to provide volume for bone graft, and the open lattice structure is designed to reduce the radiographic signature. The implant is available in multiple size options to match vertebral anatomy and is designed to restore height in the cervical spinal column during the fusion process. Implants are supplied sterile. Reusable instruments to support the surgery are provided with the implants in sterilization trays.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Innovasis HAtetracell™-C Titanium Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The HAtetracell™-C device is to be used with supplemental fixation, such as the Innovasis Oryx® Cervical Plate System. The HAtetracell™-C device is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone and is to be implanted via an anterior approach.

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

The subject device has substantially equivalent indications for use as predicate device K220875 (HAcancellous PEEK-C Porous HA PEEK Cervical IBF System).

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) as predicate device K220875 (HAcancellous PEEK-C Porous HA PEEK Cervical IBF System) and reference device K201614 (TxTiHA IBF System).

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

The FDA Guidance for Cervical Intervertebral Body Fusion Devices, Class II Special Controls Guidance Document: Intervertebral Body Fusion Device (issued June 2007) recommends the following testing:
Static and dynamic torsion testing per ASTM F2077
Static and dynamic axial compression testing per ASTM F2077
Static and dynamic compression shear testing per ASTM F2077
Static subsidence testing per ASTM F2267
Particulate analysis after dynamic testing per ASTM F1877
Static expulsion testing performed per recommendation in above guidance special controls document.
Abrasive resistance testing per ASTM F1978

N/A - no clinical data were necessary.

All testing performed met the acceptance criteria when compared with the predicate device and/or FDA cleared Cervical IBF data. The subject device is demonstrated to be as safe, as effective, and performs as well or better than the predicate device.