September 24, 2019

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

Re: K192354
Trade/Device Name: Innovasis® Gibralt® Spine System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: August 28, 2019
Received: August 29, 2019

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,

Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K192354

Device Name
Innovasis® Gibralt® Spine System

Indications for Use *(Describe)*
The Innovasis Gibralt Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt Spine System may be connected to the Innovasis Excella II® Spinal System, Excella 3® Spinal System and Excella III-D® Spinal Deformity System using rod-to-rod connectors and transitional rods. Refer to the specific system Instructions for Use for a list of their indications for use.

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

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
   Date Prepared: August 28, 2019

2. **Device Information**
   Device Name: Innovasis® Gibralt® Spine System
   Common Name: Posterior cervical screw system
   Product Codes: NKG, KWP
   Classification Name: Posterior cervical screw system (21 CFR 888.3075); Spinal interlaminar fixation orthosis (21 CFR 888.3050)
   Regulatory Class: Class II

3. **Predicate Devices**
   The primary predicate device is the Exactech, Inc. Gibralt Spine System, (K160697 – June 28, 2016).
   Innovasis, Inc. has obtained the right to manufacture and market the Gibralt Spine System as an Innovasis branded product.

4. **Device Description**
   The device description of the Gibralt Spine System is as follows:

   The Innovasis® Gibralt® Spine System is a posterior system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical, and/or upper thoracic spine. The system consists of a variety of sizes of rods, hooks, poly-axial screws and connecting components, which can be rigidly locked to the rod in various configurations. The Gibralt Spine System components are manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136), with rods being available in both titanium alloy and cobalt chrome alloy (CoCr per ASTM F1537) options.

   No modifications have been made to the design, materials or principles of operation when compared to the predicate.

5. **Intended Use**
   The Innovasis Gibralt Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed

previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt Spine System may be connected to the Innovasis Excella II® Spinal System, Excella 3® Spinal System and Excella III-D® Spinal Deformity System using rod-to-rod connectors and transitional rods. Refer to the specific system Instructions for Use for a list of their indications for use.

6. Technological Characteristics

The Gibralt Spinal System is a posterior system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical, and/or upper thoracic spine. The system consists of a variety of sizes of rods, hooks, poly-axial screws and connecting components, which can be rigidly locked to the rod in various configurations. The Gibralt Spinal System components are manufactured from titanium alloy per ASTM F136 and Cobalt Chrome per ASTM F1537. Overall, the subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, function, and packaging.

7. Performance Data

Nonclinical testing was performed on the subject Gibralt Spine System as part of K160697. The results demonstrated in K160697 that the subject Gibralt Spine System was substantially equivalent to the predicate. This information has been provided to Innovasis and no changes have been made to the system components to necessitate additional mechanical testing.

8. Conclusions

The subject Gibralt Spine System has been shown to be substantially equivalent to legally marketed predicate device for its intended use.