November 8, 2019

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

Re: K192049
Trade/Device Name: Oryx™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 13, 2019
Received: August 14, 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)*
K192049

Device Name
Oryx™ Cervical Plate System

Indications for Use *(Describe)*
The Innovasis Oryx Cervical Plate System is intended for use in anterior cervical fixation for the following indications:

i. Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
ii. Spondylolisthesis,
iii. Trauma (i.e., fracture or dislocation)
iv. Spinal stenosis,
v. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
vi. Tumor,
vii. Pseudoarthrosis; and
viii. Previous failed fusion.

The Innovasis Oryx Cervical Plate System is indicated for stabilizing the cervical spine from C2 to C7.

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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5.0 510(k) Summary Report:

Oryx™ Cervical Plate System

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

Contact: Marshall McCarty
Phone: (801) 261-2236 x8012
mmccarty@innovasis.com

Alternate: Michael Thomas
(801) 261-2236 x8002
mthomas@innovasis.com

Trade Name: Oryx™ Cervical Plate System

Common Name: Anterior cervical fixation system

Classification: Regulation No.: 21CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis
Class 2
Product Code: KWQ
Review Panel: Orthopedic
Review Team: ISDT

Primary Predicte: K030866 Synthes Anterior CSLP System

Additional: K061147 Innovasis Opteryx Anterior Cervical Plate System

Device Description: The *Oryx Cervical Plate System* consists of a number of plates and screws of varying lengths. The plates feature lordotic curvature and a transverse plane curvature for an anatomical fit. The set contains ancillary products and instruments. All implant components are machined from implant grade titanium alloy, Ti6Al4V (ELI) per ASTM F136.

Performance Data: (Non-clinical)—Performance testing on plates per ASTM F1717 for Static and Dynamic Compression Bend and Static Torsion and ASTM F543 for bone screw Axial Pull-Out, Insertion and Removal Torque and Torsional Yield Strength indicates that the *Oryx Cervical Plate System* is substantially equivalent to the predicate device.

Materials: The *Oryx* implants are machined from medical grade Ti6Al4V (ELI) per ASTM F136.

The *Oryx* instruments/accessories are machined from Surgical Stainless Steel per ASTM F899 and some have medical grade Silicone handles.

The *Oryx* sterilization trays are comprised of Anodized 5052 Aluminum and have components made of Nylon, Stainless Steel, Polypropylene, and Radel per ASTM D6394 SP031.

Intended Use: The *Oryx Cervical Plate System* is intended for use in Anterior Cervical Discectomy and Fusion (ACDF) procedures.

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

Indications for Use: The Innovasis *Oryx Cervical Plate System* is intended for use in anterior cervical fixation for the following indications:

i. Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
ii. Spondylolisthesis,
iii. Trauma (*i.e*., fracture or dislocation)
iv. Spinal stenosis,
v. Deformities or curvatures (*i.e*., scoliosis, kyphosis, and/or lordosis),
vi. Tumor,
vii. Pseudarthrosis; and
viii. Previous failed fusion.

The Innovasis *Oryx Cervical Plate System* is indicated for stabilizing the cervical spine from C2 to C7.

Comparison of the Technological Characteristics with Predicate Device:

The *Innovasis Oryx Cervical Plate System* has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the Synthes *Anterior CSLP System* (K030866) predicate.

- Design configurations are substantially equivalent.
- Applied mechanical loads are substantially equivalent.
- Materials used are substantially equivalent.
- Biocompatibility requirements have been demonstrated.
- Intended Use and Indications for Use are substantially equivalent.

Conclusion: Performance data and rationales submitted herein demonstrate that the subject *Oryx Cervical Plate System* is substantially equivalent to the predicate device with regard to design, technological characteristics, materials, performance, intended use and indications for use.