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

July 13, 2018

Re: K181063
Trade/Device Name: Kestrel™ Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 21, 2018
Received: June 22, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181063

Device Name
Kestrel™ Buttress Plate System

Indications for Use *(Describe)*
The Kestrel™ Buttress Plate System is indicated for use to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, or anterolateral spinal systems made of compatible materials. This device is not intended for load bearing applications.

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

Kestrel™ Buttress Plate 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: Kestrel™ Buttress Plate System

Common Name: Buttress Plate System

Classification: Regulation No.: 21CFR 888.3060
Class II
Product Code: KWQ
Review Panel: Orthopedic

Predicate Device: K092659 - Precision Spine *RCS Anterior Buttress Plate System*
This predicate has not been subject to a design-related recall.

Device Description: The Innovasis Kestrel™ Buttress Plate System is a temporary implant used to prevent allograft or autograft extrusion or IBFD expulsion. The Kestrel Buttress Plate System consists of plates and bone screws. The Kestrel System is also intended to provide stabilization and augment development of a solid spinal fusion. The Kestrel Buttress Plate System fixates to the anterior portion of the lumbar vertebral body. The construct may be employed alone or with other anterior, or anterolateral spinal systems made of compatible materials.

Performance Data: (Non-clinical)—Performance testing includes static and dynamic cantilever bend, torque to failure and axial pullout.

Materials: Titanium 6 Al 4V ELI per ASTM F136.

Intended Use: The Innovasis *Kestrel™ Buttress Plate System* is intended for use in the lumbar spine (L1-S1).

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 *Kestrel™ Buttress Plate System* is indicated for use to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, or anterolateral spinal systems made of compatible materials. This device is not intended for load bearing applications.

Basis for Substantial Equivalence:

The *Kestrel™ Buttress Plate System* has been subjected to risk analysis, engineering analysis and testing to recognized standards and the worst-case size has been demonstrated to be substantially equivalent to the predicate device, K092659.

The technological characteristics were found to be substantially equivalent in terms of design, sizes, materials (biocompatibility profile and processing), and mechanical strength.

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