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

November 7, 2014

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

Re: K141644
Trade/Device Name: Innovasis Cranial System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: October 8, 2014
Received: October 9, 2014

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 yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K141644

Device Name
Innovasis Cranial System

Indications for Use *(Describe)*
The Innovasis Cranial System is intended for use in selective trauma of cranial skeleton, cranial surgery and reconstructive procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

Contact: Marshall C. McCarty
Phone: (801) 261-2236
Fax: (801) 261-3758
mmccarty@innovasis.com

Date Prepared: November 7, 2014

II. Device

Name of Device: Innovasis® Cranial System
Common or Usual Name: Bone Plate, Bone Screw for Cranial Fixation

Classification: Regulation No.: 21 CFR 882.5320
Class 2, Product Code: GWO

Regulation No.: 21 CFR 882.5360
Class 2, Product Code: HBW

Regulation No.: 21 CFR 882.5250
Class 2, Product Code: GXR

III. Predicate Device

Jeil Medical Products LeForté Neuro System Bone Plate K112812
This predicate has not been subject to a design-related recall.

IV. Device Description:

The *Innovasis® Cranial System* Bone Plates are comprised of a variety of shapes and sizes intended for reconstruction, stabilization and/or rigid fixation of non load-bearing areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher). The single use devices are a variety of low profile plates and anchoring screws that fixate bone pieces together in the cranial area of the patient. The design features include:

- Commercially Pure Titanium or 6 Al 4V Titanium Alloy
- Straight and Square plates
- Double Y plates
- Burr hole plates
- Plates with Shunts
- Self-Drilling/Self-Tapping Screws
- Mesh
- Instrumentation to customize size, shape and placement of implants
- Compact sterilization tray to optimize organization of implants

V. Indications for Use

The *Innovasis® Cranial System* is intended for use in selective trauma of cranial skeleton, cranial surgery and reconstructive procedures.

VI. Comparison of Technological Characteristics with the Predicate Device

	Innovasis ICS	Jeil LeForté Neuro System
Indications	The Innovasis® Cranial System is intended for use in selective trauma of cranial skeleton, cranial surgery and reconstructive procedures.	The Leforté Neuro System is intended for use in selective trauma of cranial skeleton, cranial surgery and reconstructive procedures.
Material	ASTM F67 Commercially Pure Grade 2 Titanium (plates), Grade 3 Titanium (mesh) and ASTM F136 6Al4V Titanium for Surgical Implants (Screws)	ASTM F67 Commercially Pure Grade 2 Titanium (plates), Grade 3 Titanium (mesh) and ASTM F136 6Al4V Titanium for Surgical Implants (Screws) Additional plates offered in ASTM F67 Grade 1 and 3
Features	Straight and Square plates Double Y plates Burr hole plates Plates with Shunts Self-Drilling/Self-Tapping Screws Mesh Instrumentation to customize size, shape and placement of implants	Straight and Square plates Double Y plates Burr hole plates Plates with Shunts Self-Drilling/Self-Tapping Screws Mesh Gap, Curved, X-shape, Y, Quad and Calvarium plates Instrumentation to customize size, shape and placement of implants
Dimensions	Plates Straight, Double Y and Square, 2, 4, 6 and 12 holes; Burr hole plates 6 holes 15mm diameter, 5 holes 15mm, 6 holes 22mm and 5 holes 22mm. All plates and mesh are 0.648 +/-0.025mm Mesh 98mm x 98mm Screws: 1.6 x 3mm, 1.6 x 4mm, 1.6 x 5mm, 1.9 x 4mm	Plates Straight, Double Y and Square, 2, 4, 6 and 12 holes; Burr hole plates 6 holes 15mm diameter, 5 holes 15mm, 6 holes 22mm and 5 holes 22mm. Mesh 98mm x 98mm Above plates and mesh are 0.62mm Additional plates and mesh offered in thickness 0.3 to 0.5mm, including Gap Plates (3 sizes) Curved, X-shape, Quad and Calvarium plates are offered in other Jeil LeForté configurations Screws: 1.6 x 3mm, 1.6 x 4mm, 1.6 x 5mm, 1.9 x 4mm 2.2 x 5mm and 1.4 x 1.9mm screws are offered in other Jeil LeForté configurations.
Surface Treatment	Plate: Electropolish Screw: N/A	Plate: Anodized Screw: N/A
Sterilization	Sold Non-Sterile to be Steam Sterilized	Sold Non-Sterile to be Steam Sterilized

VII. Performance Data

(Non-clinical)—Performance testing per ASTM F543-13, F582-99 for 3 point bend (or 4 point bend), axial compression, foam axial pullout, and torque to failure and F2129-08 for corrosion support the safety of the subject devices and demonstrate that the *Innovasis Cranial System* devices should perform as intended in the specified use conditions.

Test	Test Method Summary	Results
Torsion Properties	ASTM F543-13 The torsional testing of the bone screws was performed by hand as these were very small screw samples. Both subject and predicate sample groups were tested identically so comparisons could be made accurately.	The mean torsional strength for the subject screws exceeded the strength of the predicate screws thereby demonstrating substantial equivalence.
Static Axial Pullout	ASTM F543-13	The mean pullout force for the subject screws exceeded the pullout force of the predicate screws thereby demonstrating substantial equivalence.
Static Axial Compression	A domed superior test load applied to center of specimen to measure Stiffness, Peak Force, and Displacement at Peak Force.	The mean bending stiffness, Peak Force and Displacement at deformation of the Rev. 3 subject plate exceeded the bending stiffness, Peak Force and Displacement at deformation of the predicate plate demonstrating substantial equivalence.
Static 3 Point Bend	ASTM F382-99 (08) Three-point bend instead of four-point bend testing was performed on the predicate and subject double "Y" samples due to their shortened length. Comparisons between the two groups could still be made to determine equivalence.	The mean bending stiffness of the subject plates met or exceeded the bending stiffness of the predicate plate demonstrating substantial equivalence.
Static 4 Point Bend	ASTM F382-99 (08)	The mean bending stiffness of the subject plates met or exceeded the bending stiffness of the predicate plate demonstrating substantial equivalence.
Corrosion	ASTM F2129-08	The data show the corrosion resistance of the subject plates met or exceeded the corrosion resistance of the predicate plate thereby passing the requirement in the protocol and demonstrating substantial equivalence.
Biocompatibility	A biocompatibility evaluation for the ICS implants was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices −Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.	The implants are composed of known biocompatible material [ASTM F67 Commercially Pure Titanium (plates and mesh) and ASTM F136 6Al4V Titanium for Surgical Implants (Screws)]. Testing was conducted to ensure manufacturing process did not add contamination. Test battery included Pyrogen Testing (LAL) and Cytotoxicity testing (MEM) All test results were below cutoff (pass).

VIII. Conclusions

The Innovasis Cranial System has been subjected to risk analysis, engineering analysis and testing to recognized standards. The predicate device, K112812 LeForte Neuro System was cleared based on the results of non-clinical data. In consideration of the following evaluated parameters subject and predicate device performance data were compared to support the safety of the subject devices:

- Design configurations
- Applied mechanical loads
- Product sizes and shapes
- Materials used
- Biocompatibility requirements
- Manufacturing and processing methods
- Shelf life

The evaluations demonstrate that the *Innovasis Cranial System* devices should perform as intended in the specified use conditions.