Intelligent Implant Systems, LLC
Michael Nutt
Chief Operating Officer
3300 International Airport Dr, Suite 1100
Charlotte, North Carolina 28208

April 16, 2018

Re: K173935
Trade/Device Name: Mediant™ Anterior Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 14, 2018
Received: March 15, 2018

Dear Mr. Nutt:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*
K173935

Device Name
Mediant™ Anterior Cervical Plating System

Indications for Use *(Describe)*
The Intelligent Implant Systems Mediant™ Anterior Cervical Plating System is intended for anterior cervical fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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
Intelligent Implant Systems' Mediant™ Anterior Cervical Plating System

I. Submitter: Intelligent Implant Systems, LLC
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Contact Person: Michael Nutt
Chief Operations Officer
(704) 424-1009

Date Prepared: April 11, 2018

II. Device

Name of Device: Mediant™ Anterior Cervical Plating System
Common or Usual Name: Plate and Screw Cervical Spinal Fixation System
Classification Name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Regulatory Class: II
Product Codes: KWQ

III. Predicate Devices

Primary Predicate:
Synthes Spine Anterior CSLP System (K030866, K945700)

Additional Predicate:
Spinal Innovations SPECTRUM™ Cervical Spinal System (K022997)

IV. Device Description

The Intelligent Implant Systems' Mediant™ Anterior Cervical Plating System consists of bone screws (4.0 and 4.5 mm diameter) of various lengths and a series of plates for fusion of 1-, 2-, or 3- levels of the cervical spine (C2-T1).

The device functions as follows: An appropriately sized plate is placed on the anterior aspect of the vertebral body of the cervical spine by inserting either a 4.0 mm or a 4.5 mm diameter bone screw through the cephalad and caudad holes and into the vertebral body. The device improves stability of the spine while supporting fusion.

The Mediant™ cervical plates are provided in multiple lengths from 19 mm (one-level) through 78 mm (three-level) for one-, two- and three-level fusions. The thickness of all plates is 2.2 mm and the width is 19.0 mm. All plates interface with the same cervical bone screws, which are either 4.0 mm diameter or 4.5 mm diameter. The bone screws can best be

described as semi-constrained, but can be inserted at any angle (within a ±18° angular variation) to the plate. A slider mechanism then locks the bone screws to the plate at the angle of insertion using the supplied locking pliers. The bone screw will remain fixed at the angle of insertion unless bone resorption results in high loading levels on the bone screws. If this occurs, due to the polyaxiality of the screw, the screw will re-position itself and re-lock at the new angle.

All implant components of the Mediant™ Anterior Cervical Plating system are manufactured from Ti-6Al-4V ELI alloy, conforming to ASTM F136.

V. Intended Use / Indications for Use

Intended Use:
The Mediant™ Anterior Cervical Plate implants are intended to be used as a construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during anterior fusion with a plate and screws.

Indications for Use:
The Intelligent Implant Systems MEDIANT™ Anterior Cervical Plating System is intended for anterior cervical fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

VI. Comparison of Technological Characteristics with the Predicate Devices

The Mediant™ Anterior Cervical Plate System and the predicate devices are all anterior systems utilizing screw and plate fixation for stabilization of spinal segments. The subject and predicate devices all have the following technological characteristics:

- Bone screws attach the plate to vertebral bodies
- Locking mechanism secures screws to the plate
- Plates are low profile and available in a variety of sizes to conform to patient anatomy

The following technological differences exist between the subject and predicate devices:

- The Mediant™ Anterior Cervical Plating system utilizes a locking mechanism which is secured by moving a slider to the locked position with a pair of locking pliers. This contrasts with the predicate CSLP device which uses a locking screw.
- The Mediant™ Anterior Cervical Plating bone screws can be inserted at the angle desired by the surgeon, within a circumferential range of ± 18°. Both predicate devices have a smaller angular range of motion.

VII. Performance Data

The following performance data are provided in support of the substantial equivalence determination:

Mechanical Testing:
To validate the strength and safety of the system components, testing was conducted according to methods defined in ASTM F 1717-15, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model". The types of testing performed are listed below:

1. Static Compression Bending
2. Static Torsional Bending
3. Dynamic Compression Bending

The testing revealed that the mechanical properties of the Mediant™ cervical plating system were comparable to published values for anterior plating systems and to the predicate devices.

VIII. Conclusions

The design of the Mediant™ Anterior Cervical Plate system is similar to the predicate devices, it functions in a similar manner, and its mechanical properties are comparable. Thus, the Mediant™ Anterior Cervical Plating system was found to have a safety and effectiveness profile similar to the predicate devices.