April 9, 2020

MiRus, LLC
Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway, Suite 108
Marietta, Georgia 30067

Re: K191867
Trade/Device Name: ATLAS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 9, 2020
Received: March 10, 2020

Dear Jordan Bauman:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K191867

Device Name

ATLAS™ Plating System

Indications for Use *(Describe)*

The ATLAS™ Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies of small bones and bone fragments in adult and pediatric patients.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

I. SUBMITTER

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II. OFFICIAL CORRESPONDENT

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Tel: (678) 324-6272
Fax: (678) 401-5607

III. DATE PREPARED

April 9, 2020

IV. DEVICE

Name of Device	ATLAS™ Plating System
Common Name	Fixation Bone Screw System
Classification Name	21 CFR §888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3040 Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Product Codes	HRS, HWC
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Primary Predicate
MINI MAXLOCK Extreme Plating System (K121437)

Additional Predicate
ATLAS™ Plating System (K190415)
ORTHOLOC® 3Di Small Bones Plating System (K163039)

Reference Device
EUROPA™ Pedicle Screw System (K130337)

VI. DEVICE DESCRIPTION

The ATLAS™ Plating System is a metallic plate and screw system for treatment and fixation of fractures, fusions and osteotomies of bones in the Foot, Ankle, Hand, and Wrist of children (2-12 years), adolescents (12-21 years), and adults. The screws are available in different diameters from Ø2.7mm to Ø5.5mm, non-locking or locking configurations with lengths ranging from 8mm to 60mm. All screws are manufactured from Titanium alloy (Ti-6Al-4V ELI per ASTM F136-13). The plates are available in different geometries to accommodate different patient and bone anatomies. The plates are manufactured from MoRe® alloy (Molybdenum-47.5Rhenium Alloy per ASTM F3273-17).

VII. INDICATIONS FOR USE

The ATLAS™ Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies of small bones and bone fragments in adult and pediatric patients.

VIII. PREDICATE DEVICE COMPARISON

The intended use and technological characteristics of the ATLAS™ Plating System are the same as the predicate devices except for the plate material which is manufactured from MoRe® alloy (Molybdenum-47.5Rhenium Alloy per ASTM F3273-17) for enhanced strength.

IX. PERFORMANCE DATA

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

- Mechanical testing for screws (ASTM F543-17)
- Mechanical testing for plates (ASTM F382-17)

X. CONCLUSIONS

Performance data demonstrate that the ATLAS™ Plating System is substantially equivalent legally marketed predicate devices.