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

December 18, 2018

Re: K182989
Trade/Device Name: AURORA™ Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 26, 2018
Received: October 29, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.12.18 14:54:04 -05'00'

For;
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

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)*

K182989

Device Name

AURORA™ Screw System

Indications for Use *(Describe)*

The AURORA™ Screw System is intended to aid in the repair of fractures, fusions and osteotomies of bones and bone fragments.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

II. OFFICIAL CORRESPONDENT

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Marietta, Georgia 30067
Tel: (678)-324-6272
Fax: (678) 401-5607

III. DATE PREPARED

October 26, 2018

IV. DEVICE

Name of Device	AURORA™ Screw System
Common Name	Fixation Bone Screw System
Classification Name	21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Product Codes	HWC
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Osteomed Cannulated Screw System (K151021 - primary predicate)
MAXTORQUE™ Screw System (K131324)
MAXTORQUE™ MINI Cannulated Screw System (K082574)
CSS Cannulated Screw System (K060428)

VI. DEVICE DESCRIPTION

The AURORA™ Screw System is a bone screw system consisting of solid and cannulated screws for treatment and fixation of fractures, fusions and osteotomies of bones in the Foot, Ankle, Hand, and Wrist.

The screws are available in different diameters from Ø2.7mm to Ø7.5mm, are solid or cannulated with lengths ranging from 18mm to 160mm. All screws are manufactured from

Ti-6Al-4V ELI alloy (ASTM F136-13). Optional washers are available for certain screws; the washers are also made from Ti-6Al-4V ELI alloy (ASTM F136-13).

The screws and washers are intended to be implanted until bone healing. Implants are single use and the system is provided non-sterile.

VII. INDICATIONS FOR USE

The AURORA™ Screw System is intended to aid in the repair of fractures, fusions and osteotomies of bones and bone fragments.

VIII. PREDICATE DEVICE COMPARISON

The documentation provided shows that the MiRus™ AURORA™ Screw System is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics and labeling.

IX. PERFORMANCE DATA

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

- Mechanical testing (ASTM F543)
- Engineering Analysis

X. CONCLUSONS

The MiRus™ AURORA™ Screw System does not raise any new questions of safety or efficacy when compared to the predicate device(s). The AURORA™ Screw System has demonstrated that it is substantially equivalent in mechanical performance, indications for use, intended use, technological characteristics, materials and labeling to legally marketed predicate devices.