SIG Medical Corp.
% Jennifer Palinchik
President
JALEX Medical, LLC
30331 Clemens Road, Suite #5D
Westlake, Ohio 44145

November 16, 2018

Re: K182179
Trade/Device Name: AdvantageRib Anterior 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: October 22, 2018
Received: October 23, 2018

Dear Jennifer Palinchik:

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: 2018.11.16 16:49:56 -05'00'

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)*
K182179

Device Name
AdvantageRib Anterior System

Indications for Use *(Describe)*

The AdvantageRib Anterior System is intended for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitted By: SIG Medical Corp.
238 E. Chocolate Ave. Suite 2
Hershey, PA 17033

Date: 10/22/2018

Contact Person: Jennifer Palinchik, President
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: AdvantageRib Anterior System
Common Names: Plate, Fixation, Bone
Screw, Fixation, Bone
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Smooth or threaded metallic bone fixation fastener
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3040
Regulatory Class: Class II
Product Codes: HRS, HWC
Reviewing Panel: Orthopedic
Primary Predicate Device: Zimmer-Biomet Microfixation RibFix Blue Thoracic Fixation System (K142823 and K151173)
The primary predicate device has never been subject to a recall.
Reference Predicate Device: Synthes MatrixRIB Endo Thoracoscopic Rib Plating System (K141241)

Device Description:

The AdvantageRib Anterior System is composed of commercially pure titanium locking bone plates per ASTM F67 and titanium alloy locking and non-locking screws per ASTM F1472 that provide rigid fixation in instances of fractures and osteotomies in normal and osteoporotic bone. The implant and associated screws are provided to the end user in non-sterile packaging, in a variety of sizes and lengths.

Intended Use:

The AdvantageRib Anterior System is intended for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Summary of Technological Characteristics:

The AdvantageRib Anterior System shares many similarities to the predicate device. These similarities include:

- Intended use
- Materials
- Design features
- Dimensions
- Function
- Surgical technique and labeling

Clinical and Non-Clinical Performance Data:

Clinical testing is not necessary to demonstrate substantial equivalence.

Performance was evaluated in accordance with ASTM F382, ASTM F543, and ASTM F2193. Engineering and geometric analysis was conducted to demonstrate substantial equivalence to the predicate device.

Conclusion:

Based on the intended use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence and does not raise additional questions of safety or effectiveness.