



February 14, 2019

SIG Medical Corporation
% Lauren Smith
Project Engineer
JALEX Medical, LLC.
30311 Clemens Road, Suite #5D
Westlake, Ohio 44145

Re: K183317

Trade/Device Name: AdvantageRib 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: January 14, 2019

Received: January 15, 2019

Dear Lauren Smith:

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,

 Shumaya Ali -S

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

Enclosure

Indications for Use

510(k) Number (*if known*)

K183317

Device Name
AdvantageRib System

Indications for Use (*Describe*)

The AdvantageRib 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.

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510(k) Summary

Submitted For:	SIG Medical Corp. 238 E. Chocolate Ave. Suite 2 Hershey, PA 17033
Date:	02/14/2019
Contact Person:	Lauren Smith, Project Engineer, JALEX Medical
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Contact Address:	30311 Clemens Rd. Suite 5D, Westlake, OH 44145
Device Trade Name:	AdvantageRib System
Common Names:	Plate, Fixation, Bone and Screw, Fixation, Bone
Regulation Names:	Single/multiple component metallic bone fixation appliances and accessories and 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:	MatrixRIB Endo Thorascopic Rib Plating System (K141241)

Device Description:

The AdvantageRib System consists of bridges (with locking posts) and locking caps for the thoracoscopic fixation and stabilization of ribs. These implants are manufactured from commercially pure titanium and titanium alloys (Ti-6Al-7N per ASTM F1295 and Ti-6Al-4V per ASTM F136 or ASTM F1472). The system is comprised of the following implants:

- Titanium alloy AdvantageRib Bridge with threaded locking posts
- Commercially pure locking caps

When fully assembled, the bridge is placed on the underside of the rib, the threaded locking posts extends through pre-drilled holes in the rib, and the locking caps are fixed to the locking post on the anterior side of the rib. The combined threaded locking post/locking cap provides for fixation of the bridge.

Indications for Use:

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

Substantial Equivalence:

The AdvantageRib System has the same intended use, indications for use, principles of operation, and technological characteristics of the predicate. The modifications are not being made as a corrective action for any quality or compliance issues with the predicate version. Modifications summarized in the following table do not raise new questions of safety or effectiveness. Therefore, the AdvantageRib System is substantially equivalent to the predicate.

Item	Modified AdvantageRib System	MatrixRIB Endo Thorascopic Rib Plating System	Comparison
Product Code	HRS, HWC	HRS, HWC	Same
Classification Name	Plate, fixation, bone and Screw, fixation, bone	Plate, fixation, bone and Screw, fixation, bone	Same
Class	II	II	Same
Indications for Use	The AdvantageRib System is intended for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.	The Synthes Matrix Rib Fixation System is indicated for the fixation and stabilization of rib fractures, fusions and osteotomies of normal and osteoporotic bone.	Same
Materials	Bridge (plate) and locking posts: Ti-6Al-7N per ASTM F1295, Ti-6Al-4V per ASTM F136, Ti-6Al-4V per ASTM F1472 Locking cap and washer: Commercially Pure Titanium Grade 4 per ASTM F67	Plate and locking posts: Ti-6Al-7N per ASTM F1295 Locking cap: Commercially Pure Titanium Grade 4 per ASTM F67	The modified AdvantageRib System includes the option of manufacturing the bridges (plates) and locking posts from Ti-6Al-4V per ASTM F136 or Ti-6Al-4V per ASTM F1472.
Design Features	Optional washer Increased lengths of locking posts and locking caps with internal X-drive feature.	No washer included Locking caps with external hex drive feature.	Optional washer distributes the load of tightening the locking posts in poor bone quality. Increased length of locking posts allows for increased thread engagement. Locking cap modified drive feature minimizes soft tissue obstruction.
Sterilization	Steam Sterilization (All implants and instruments)	Gamma radiation (plates and locking posts), Steam sterilization (locking caps and instruments)	All implants can be steam sterilized and provided non-sterile.



Non-Clinical Testing:

The AdvantageRib System is identical in geometry and manufacturing process to the predicate device. Dynamic and static testing was performed on the bridge, locking post, locking cap construct demonstrating that neither the material or dimensional changes introduced a new worst case. Sterilization validation was performed on the subject device per ISO 14937:2009 Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices to establish SAL of 10^{-6} .

Conclusion:

The conclusions drawn from the nonclinical testing demonstrates that the device is as safe and as effective as the identified predicate.