DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 25, 2016

Extremity Medical, LLC
Mr. Brian Smekal
VP, Regulatory Affairs and Quality Assurance
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

Re: K160191
Trade/Device Name: Align Anterior Ankle Fusion Plate
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 26, 2016
Received: January 27, 2016

Dear Mr. Smekal:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160191

Device Name
Align Anterior Ankle Fusion Plate

Indications for Use *(Describe)*
The Align Anterior Ankle Fusion Plate is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 of Safety and Effectiveness:

Align Anterior Ankle Fusion Plate

Submitter	Extremity Medical, LLC. 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054
Contact Person	Brian Smekal, MS, RAC VP, Regulatory Affairs and Quality Assurance Phone: (973) 588-8988 Email: bsmekal@extremitymedical.com
Date Prepared	March 21, 2016
Trade Name	Align Anterior Ankle Fusion Plate
Classification Name and Number	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories; 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	HRS (plate, fixation, bone); HWC (screw, fixation, bone)
Predicate Devices	K081934 – Extremity Medical Compression Screw K133691 – Extremilock Ankle Plating System K132591 – Maxlock Extreme System K121425 – Ortholoc 3Di Ankle Fusion Plating System and Ortholoc Bone Screws
Device Description	The Align Anterior Ankle Fusion Plate is a bone fixation device consisting of an anatomical, anterior tibia plate and various locking and non-locking screws and a set of instruments used for implant site preparation and delivery. The plate is available in three configurations, a slim plate and a 2-tab plate (available in two widths). A central hole in the plate allows for angled placement of a “home run” screw to obtain axial compression across the tibioltalar (TT) or (tibiotalarcalcaneal) (TTC) joints. The 2-tab plate is designed with an anterior “window” to allow autologous grafting of the TT and visualization of fusion under fluoroscopy.
Indications for use	The Align Anterior Ankle Fusion Plate is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.
Statement of Technological Comparison	The Align Anterior Ankle Fusion Plate and predicate devices are equivalent in terms of indications for use, design, and material mechanical properties.
Non-clinical Testing	Bench testing including pull-out, torque on the screws and engineering analysis was used to demonstrate that the mechanical strength of the subject device was substantially equivalent to the predicate device.
Clinical Testing	No clinical testing was performed.
Conclusion	The Align Anterior Ankle Fusion Plate is substantially equivalent to its predicate device. This conclusion is based upon indications for use, principles of operation, design, and mechanical test data.