January 22, 2021

Advanced Research Medical, LLC
% Kyle Kovach
Quality and Regulatory Engineer
JALEX Medical
27865 Clemens Rd., Suite #3
Westlake, Ohio 44145

Re: K203373
Trade/Device Name: Advanced Research Medical Trident SI Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: November 11, 2020
Received: November 16, 2020

Dear Kyle Kovach:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203373

Device Name
Advanced Research Medical Trident SI Screw System

Indications for Use *(Describe)*
The Advanced Research Medical Trident SI Screw System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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510(k) Summary

Submitted By: Advanced Research Medical, LLC
1515 Hwy 13 East
Burnsville, MN 55337

Date: 11/11/2020

Contact Person: Kyle Kovach, Quality and Regulatory Engineer
Contact Telephone: (440) 787-5832
Contact Fax: (440) 933-7839

Device Trade Name: Advanced Research Medical Trident SI Screw System
Device Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: OUR

Primary Predicate Device: L&K Biomed Co., Ltd. PathLoc-SI Joint Fusion System (K153656)

Device Description:

The Advanced Research Medical Trident SI Screw System consists of screws manufactured from Ti-6Al-4V ELI per ASTM F136. The screws are available in a variety of lengths and diameters to accommodate varying patient anatomy.

Indications for Use:

The Advanced Research Medical Trident SI Screw System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Summary of Technological Characteristics:

The Advanced Research Medical Trident SI Screw System and the predicate have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate device technological characteristics is provided in this submission in Section XIV Substantial Equivalence. A condensed comparison table is also presented below. There are no differences in technological characteristics that raise questions of safety and efficacy.

Table 1: Dimensions and Technological Characteristics Comparison

Item	Advanced Research Medical Trident SI Screw System	L&K Biomed Co., Ltd. PathLoc-SI Joint Fusion System (K153656)
Classification Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener
Regulation	21 CFR 888.3040	21 CFR 888.3040
Product Code	OUR	OUR
Screw Lengths	30 – 90 mm in 5 mm increments	30 – 70 mm in 5 mm increments

Screw Diameters	Ø6.0, 13.0 mm	Ø6.0, 7.0, 12.0 mm
Material	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136

Non-Clinical Testing:

The implants, instruments, and case are supplied non-sterile and must be sterilized prior to use. These components of the system were adopted into a validated cleaning procedure and steam sterilization protocol.

Biocompatibility testing was not required for this device. The screw system is manufactured from Ti-6Al-4V ELI per ASTM F136, while the associated instrumentation is manufactured from medical grade stainless steel per ASTM F899, A269, and F138, silicone, and polyphenylsulfone (PPSU). The screw system material is recognized by the FDA and cleared for implantation. The predicate device is also made from the same material cleared for implantation. The type and duration of patient contact (permanent >30 days) is identical to the predicate device. Steam sterilization, which is an industry standard for these types of implants and instruments, does not adversely affect the raw materials. Biocompatibility is therefore not adversely affected.

Clinical testing was not required for this device. Substantial equivalence to the predicate device was determined through comparison of mechanical testing results, materials, indications and intended uses, and device function.

Substantial equivalence is supported by the results of mechanical testing including static and dynamic cantilever bending per ASTM F2193 and axial pullout, driving torque, and torsional strength per F543. Mechanical testing methods, data, and reports are provided in this submission.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.