DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 21, 2017

Arrowhead DE, LLC
Thomas Twardzik
VP-Marketing and Operations
328 Poplar View Lane East, Suite 2
Collierville, Tennessee 38017

Re: K162032
Trade/Device Name: Arrowhead Mini-Rail Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, JDW, HTY
Dated: January 18, 2017
Received: January 23, 2017

Dear Thomas Twardzik:

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 Part 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" (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 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,

Vincent J. Devlin -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162032

Device Name
Arrowhead Mini-Rail Fixator

Indications for Use *(Describe)*
The Arrowhead Mini-Rail Fixator is indicated for stabilizing various fractures including open and comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

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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Section 1: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Arrowhead Mini-Rail Fixator 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor:	Arrowhead Medical Device Technologies, LLC 328 Poplar View Lane East, Suite 2 Collierville, TN 38017
Contact Person:	Thomas J. Twardzik Vice President, Marketing and Operations Office: (901) 853-4366 Fax: (206) 222-9173 Email: Tom@ArrowheadDevices.com
Date of Submission:	July 20, 2016
Proprietary Name:	Arrowhead Mini-Rail Fixator
Common Name	External Fixator and fixations screws
Regulatory Class	Class II
Regulation	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Product Code and Panel	KTT Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component - Single/multiple component metallic bone fixation appliances and accessories. HTY Pin, Fixation, Smooth - Smooth or threaded metallic bone fixation fastener. JDW Pin, Fixation, Threaded - Smooth or threaded metallic bone fixation fastener. Orthopedic

Predicate Devices	SIDEKICK Rail Fixator	K080071
	Apex Kirschner Wires and Steinmann Pins	K121004
	ST.A.R.90 F4 External Fixation Screws With Hydroxyapatite	K150661

Device Description

The Arrowhead Mini-Rail Fixator is a unilateral fixator that provides a stable solution for fractures, for lengthening of bones and for correcting deformities.

The Fixation Clamps are capable of controlled linear translation along the rail and of applying either compression or distraction forces. Because the Fixation Clamps can move along the rail independently of one another, a distraction force can be applied at one location along the Fixation Rail and distraction forces applied at another location along the same Fixation Rail. The Fixation Clamps are capable of securing Fixation Screws with a diameter of 1.6mm to 3.0mm. The rail system and clamps are manufactured from aluminum and stainless steel. The fixation screws are stainless steel and available with and without hydroxyapatite coating. The fixation screws are provided sterile while the non-implantable fixator components are provided non-sterile.

Intended Use

The Arrowhead Mini-Rail Fixator is indicated for stabilizing various fractures including open and comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

Performance Data

The Arrowhead Mini-Rail Fixator was evaluated using Finite Element Analysis (FEA) in accordance with ASTM F1541-02. The FEA testing demonstrated that The Arrowhead Mini-Rail Fixator components met performance requirements and are equivalent in strength and stiffness to the predicate device.

Technological Characteristics and Substantial Equivalence

The Arrowhead Mini-Rail Fixator is technologically substantially equivalent to predicate devices in terms of intended use, material, design, mechanical performance and safety. The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.