September 22, 2020

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

Re: K200123
Trade/Device Name: Accessories for the SixFix® Hexapod 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
Dated: August 18, 2020
Received: August 19, 2020

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. 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,

Ting Song
Assistant Director
DHT6A: Division of Joint Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200123

Device Name
Accessories for the SixFix® Hexapod Fixator

Indications for Use *(Describe)*
INDICATIONS for Accessories for the SixFix Hexapod Fixator (Reduction Struts, Foot Arches with Locking Hinges, Motion Hinge, Variable Angle Clamps)

The SixFix® Hexapod Fixator is intended to be used for post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudo-arthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

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 K200123
Accessories for the SixFix® Hexapod Fixator

I. Submitter:

Arrowhead Medical Device Technologies, LLC 328
Poplar View Lane East, Suite 2 Collierville, TN 38017

Contact Person: Thomas J. Twardzik
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Email: INFO@ArrowheadDevices.com

Date of Summary: September 17, 2020

II: Device

Proprietary Name: Accessories for the SixFix® Hexapod Fixator
Common Name: External Fixator
Regulatory Class: Class II
Regulation:

21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Device Product Codes: KTT

Panel: Orthopedic

III. Predicate Devices

Device	Manufacturer	510(k) No.	Clearance Date
Primary Predicate			
SixFix Hexapod Fixator	AMDT	K190069	May 14, 2019
Secondary Predicates			
TL-HEX TRUELOK External Fixation System	Orthofix Srl	K141078	September 2, 2014
Hoffman LRF System	Stryker GmbH	K161753 K163656 K182968	November 15, 2016 April 14, 2017 January 25, 2019

IV. Device Description

The SixFix Hexapod Fixator is a multilateral circular external fixation system. The system includes the following external fixator elements: rings, arches, foot rockers, struts, threaded rods, reduction struts, and assembly accessories. All the elements are provided non-sterile and are for single use only.

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V. Intended Use

INDICATIONS for Accessories for the SixFix Hexapod Fixator (Reduction Struts, Foot Arches with Locking Hinges, Motion Hinge, Variable Angle Clamps)

The SixFix®Hexapod is intended to be used for post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures vrequiring distraction; open and closed fracture fixation; pseudo-arthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

VI. Comparison of Technological Characteristics with the Predicate Devices

The accessories used with the SixFix Hexapod Fixator are technologically substantially equivalent to predicate devices in terms of intended use, material, design, mechanical performance, and safety. Comparisons confirmed that the accessories used with the SixFix Hexapod Fixator are substantially equivalent when compared to those accessories used with the predicate device. The design characteristics of the accessories used with 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.

VII. Performance Data

The SixFix Reduction Struts were compared to the predicate device in accordance to ASTM F1541 static axial compression testing. The SixFix Reduction Struts exhibited results comparable to the predicate device in addition to possessing a slightly greater stiffness than the predicate device. Because there are no new concerns related to safety and effectiveness, it can be determined that the SixFix Reduction Struts are substantially equivalent to the predicate devices.

VIII. Conclusions

A review of the device indications, material composition, external element design, and technological characteristics confirmed that the accessories used with the SixFix Hexapod Fixator are substantially equivalent to the predicate devices. While the accessories used with the SixFix Hexapod Fixator are not identical to the predicate devices, comparisons of the subject and predicate device confirmed that any differences between the subject device and predicate do not render the device NSE as there is not a new intended use; and any differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate device. Therefore, it is concluded that the accessories used with the SixFix Hexapod Fixator are substantially equivalent to the predicate devices.