May 14, 2019

Arrowhead DE, LLC
Patrick Mullaney
President/CEO
328 Poplar View Lane East, Suite 2
Collierville, Tennessee 38017

Re: K190069

Trade/Device Name: SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)

Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: KTT, HTY, OSN
Dated: April 17, 2019
Received: April 18, 2019

Dear Patrick Mullaney:

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,

Peter G. Allen -S

FOR CAPT Raquel Peat, PhD, MPH, USPHS
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
Indications for Use

The SixFix Hexapod Fixator and Deformity Analysis and Correction Software (DACS) are intended to be used as components of the Smith & Nephew Taylor Spatial Frame external fixation system that is indicated for the following:

- 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.

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff

PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
I. Submitter:
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: INFO@ArrowheadDevices.com

Date of Summary: May 7, 2019

II: Device
Proprietary Name: SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)
Common Name: Orthopaedic Software for Treatment and Instrumentation
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 Codes: KTT, HTY, and OSN
Panel: Orthopedic

III. Predicate Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>510(k) No.</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Predicate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taylor Spatial Frame</td>
<td>Smith &amp; Nephew</td>
<td>K093047</td>
<td>09/27/2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K970748</td>
<td>05/09/1997</td>
</tr>
<tr>
<td>Secondary Predicates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deformity Analysis and Correction Software (DASC) and Instrumentation</td>
<td>Arrowhead Medical Device Technologies, LLC</td>
<td>K180539</td>
<td>08/13/2018</td>
</tr>
<tr>
<td>Ilizarov External Fixation Wires</td>
<td>Smith &amp; Nephew</td>
<td>K870961</td>
<td>03/19/1987</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K962808</td>
<td>08/19/1996</td>
</tr>
</tbody>
</table>
IV. Device Description

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

The system is designed such that gradually adjusting the lengths of the struts in relation to one another alters the orientation of the rings and, consequently, the bone segments connected to the rings by half-pins and wires during the treatment period in order to achieve the patient’s treatment goals.

The Deformity Analysis and Correction Software is an optional software component and is used to assist the physician in calculating the lengths of the struts connecting the rings to manipulate the bone fragments. The software receives inputs from the physician and allows the physician to visualize the moving bone position. The program computes the strut lengths necessary to implement any desired translation and/or rotation required by the surgeon.

V. Intended Use

The SixFix™ Hexapod and Deformity Analysis and Correction Software (DACS) are 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

The SixFix™ Hexapod Fixator is technologically substantially equivalent to predicate devices in terms of intended use, material, design, mechanical performance and safety. Testing and analyses confirmed that the Hexapod™ Fixator is substantially equivalent when compared to the predicate device. 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.

The subject device and predicate devices are optional software programs that are used with a spatial frame external fixation system. The functions performed by the SixFix™ DACS match the functions performed by the predicate DACS (K180539). Software validation confirmed that the DACS should perform as intended.
VII. Performance Data

Static and dynamic mechanical testing were performed in support of the submission. The testing confirmed that the subject SixFix™ Hexapod Fixator is substantially equivalent to the predicate device.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a Moderate Level of Concern. Documentation for Moderate Level of Concern was provided as follows.

- Device Hazard Analysis
- Software Requirements Specification
- Architectural Design Charts
- Software Design Specification Traceability Analysis
- Software Development Environment Description
- Software Verification Plan and Protocol
- Variety Testing Software Verification Protocol
- Cybersecurity Risk Analysis Report
- Off-the-Shelf Software Analysis
- Software Release Record
- Unresolved Anomaly Report
- Verification and Validation Documentation

From the evidence submitted in this 510(k) for the software, the Deformity Analysis and Correction Software (DACS) demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicates. The design characteristics of the subject system software do not raise any new types of questions of safety or effectiveness.

VIII. Conclusions

A review of the device indications, material composition, external element design, and technological characteristics confirmed that the SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software are substantially equivalent to the predicate device. While the SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software are not identical to the predicate device, 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 SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software is substantially equivalent to the predicate devices.