August 13, 2018

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

Re: K180539
Trade/Device Name: Deformity Analysis and Correction Software (DACS) and Instrumentation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: OSN, KTT
Dated: July 5, 2018
Received: July 13, 2018

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/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,

Jesse Muir -S
2018.08.13 18:43:19 -04'00'

In lieu of,
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)*
K180539

Device Name
Deformity Analysis and Correction Software and Instrumentation

Indications for Use *(Describe)*
The Deformity Analysis and Correction Software (DACS) and Instrumentation 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.

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510(k) Summary

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: INFO@ArrowheadDevices.com

Date of Submission:

February 26, 2018

Proprietary Name:

Deformity Analysis and Correction Software (DACS) and Instrumentation

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

Device Product Code and Panel

OSN Software For Diagnosis/Treatment
KTT Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component - Single/multiple component metallic bone fixation appliances and accessories.

Orthopedic

Predicate Devices

Device	Manufacturer	510(k) No.	Clearance Date
Taylor Spatial Frame (TSF)	Smith & Nephew	K110069 K093047 K970748	02/08/2011 09/27/2010 05/09/1997
TL-HEX Truelok Hexapod System	Orthofix	K141078 K152171	09/02/2014 09/28/2015
OrthoHub External Fixator Software	OrthoHub	K140550	08/25/2014

510(k) Summary

Device Description

The Deformity Analysis and Correction Software (***DACS***) and Instrumentation 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. The instrumentation includes Radiopaque Fiducial Markers which are attached to the Smith & Nephew Taylor Spatial Frame external fixator.

Intended Use

The Deformity Analysis and Correction Software (***DACS***) and Instrumentation are intended to be used as component of the Smith & Nephew Taylor Spatial Frame (TSF) 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.

510(k) Summary

Technological Characteristics

The Deformity Analysis and Correction Software (***DACS***) and Instrumentation are substantially equivalent to predicate devices in terms of intended use, product technical characteristics and performance characteristics. Software documentation was conducted according to FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (Document issued on: May 11, 2005). The design characteristics of the subject system software do not raise any new types of questions of safety or effectiveness.

Functional testing of the Deformity Analysis and Correction Software (***DACS***) and Instrumentation was conducted and summarized in Exhibit 36 Verification and Validation Documentation - SWVR-AMD-0101 Software Verification Report. Performance and accuracy testing were performed to test the ability of the Deformity Analysis and Correction Software (***DACS***) and Instrumentation to produce correct results under different variations of bone deformities, anatomical orientations, and device combinations. This testing protocol was executed against a variety of CAD-generated image sets and a Smith & Nephew Taylor Spatial Frame x-ray image set. The known inputs for each image (device types and strut settings) was compared to the results calculated by the Deformity Analysis and Correction Software (***DACS***) and Instrumentation. Testing with these image pairs demonstrated that the Deformity Analysis and Correction Software (***DACS***) and Instrumentation is capable of successfully correcting the variety of deformities it may encounter in the clinical setting.

From the evidence submitted in this 510(k), the Deformity Analysis and Correction Software (***DACS***) and Instrumentation demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicates.

510(k) Summary

Substantial Equivalence and Conclusions

A review of the device intended use, product technical characteristics and performance characteristics confirmed that the Deformity Analysis and Correction Software and Instrumentation is substantially equivalent to the predicate device. While the Deformity Analysis and Correction Software and Instrumentation is not identical to the predicate device software, comparisons of the subject and predicate device software confirmed that any differences between the subject device and predicate software 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 Deformity Analysis and Correction Software and Instrumentation is substantially equivalent to the Smith & Nephew Taylor Spatial Frame Software.

Substantial Equivalence Comparison Table

Parameter	Deformity Analysis and Correction Software and Instrumentation	TSF System and Software	TL-HEX Truelok Hexapod System and Software	OrthoHub External Fixator Software
Manufacturer	Arrowhead Medical Device Technologies, LLC	Smith & Nephew, Inc. Orthopaedic Division	Orthofix	OrthoHub
510(k) Number(s)	K180539	K110069, K093047, K970748	K141078, K152171	K140550
Regulation	CFR 888.3030	CFR 888.3030	CFR 888.3030	CFR 888.3030
Product Codes	KTT, OSN	KTT, OSN	KTT, OSN	OSN

510(k) Summary

Substantial Equivalence Comparison Table

Parameter	Deformity Analysis and Correction Software and Instrumentation	TSF System and Software	TL-HEX Truelok Hexapod System and Software	OrthoHub External Fixator Software
Intended Use	The Deformity Analysis and Correction Software (***DACS***) and Radiopaque Fiducial Markers are intended to be used as component of a 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.	The Smith & Nephew Spatialframe.com software is intended to be used as a component of multilateral external fixation systems that are 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; pseudoarthrosis 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.	The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of nonunion or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. Within this range, indications include: • 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 • Pseudoarthrosis 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 non-unions	The OrthoHub External Fixator Software is used with Smith & Nephew Taylor Spatial Frame (TSF) rings and struts for the treatment of traumatic or reconstructive tibia deformities. It is used to generate a prescription of strut adjustments to provide to the patient.

510(k) Summary

Substantial Equivalence Comparison Table

Parameter	Deformity Analysis and Correction Software and Instrumentation	TSF System and Software	TL-HEX Truelok Hexapod System and Software	OrthoHub External Fixator Software
Software				
Use	Optional	Optional	Optional	Optional
Inputs	Surgeon inputs based on x-ray position	Surgeon inputs based on x-ray position	Surgeon inputs based on x-ray position	
Visualization	Visualize the moving bone	Visualize the moving bone	Visualize the moving bone	
Image for Input	Orthogonal A/P, M/L radiograph after fixator installed on patient	Orthogonal A/P, M/L radiograph after fixator installed on patient	Orthogonal A/P, M/L radiograph after fixator installed on patient	Orthogonal A/P, M/L radiograph after fixator installed on patient
Data to Input	Deformity Measurements Mount Parameters Frame Components Strut Settings	Deformity Measurements Mount Parameters Frame Components Strut Settings	Deformity Measurements Mount Parameters Frame Components Strut Settings	Deformity Measurements Mount Parameters Frame Components Strut Settings
Means of Measure and Input	Software image recognition and hardware identification. Graphical input. Single item of manual entry.	Manual measurement of radiograph. Manual entry.	Manual measurement of radiograph. Manual entry. Limited graphical input	Manual measurement of radiograph. Limited graphical input. Manual entry.
Output	Patient prescription with details for frame adjustment.	Patient prescription with details for frame adjustment.	Patient prescription with details for frame adjustment.	Patient prescription with details for frame adjustment.

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