



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Phalanx Innovations  
% Ms. Cheryl Wagoner  
Principal Consultant  
Wagoner Consulting LLC  
P.O. Box 15729  
Wilmington, North Carolina 28408

April 26, 2016

Re: K160194

Trade/Device Name: StarFuse Interphalangeal Pin  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HTY  
Dated: April 8, 2016  
Received: April 11, 2016

Dear Ms. Wagoner:

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 yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160194

Device Name

StarFuse Interphalangeal Pin

Indications for Use (Describe)

The StarFuse Interphalangeal Pin is indicated for use with osteotomies, arthrodeses, and reconstruction procedures involving the correction of the lesser digits of the toes.

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**  
(as required by 21 CFR 807.92)

Date Prepared	April 8, 2016
Manufacturer	Phalanx Innovations
Address	200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
Contact Person	Daniel Lanois General Manager
Address	Phalanx Innovations 200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
email	daniel@phalanxinnovations.com

Trade Name	StarFuse Interphalangeal Pin	
Common Name	Intramedullary Bone Fastener	
Panel Code	Orthopaedics/87	
Classification Name	Smooth or threaded metallic bone fixation fastener	
Class	Class II	
Regulation Number	21 CFR 888.3040	
Product Code	HTY	
<b>Name of Predicate Device</b>	<b>510(k) #</b>	<b>Manufacturer</b>
ARROW-LOK Digital Fusion System	K112675	Arrowhead Medical Device Technologies, LLC

<b>Description</b>	The StarFuse Interphalangeal Pin is a fusion device available in a range of profile diameters and lengths as well as straight or pre-bent options. Implants are made from 316LVM Stainless Steel per ASTM F138 and range in size from 3 to 4 mm in diameter and 16 to 30 mm in length.
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<b>Indications and Intended Use</b>	StarFuse Interphalangeal Pin is indicated for use with osteotomies, arthrodeses, and reconstruction procedures involving the correction of the lesser digits of the toes.
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<b>Technological Characteristics and Substantial Equivalence</b>	Documentation was provided to demonstrate that the Subject device, is substantially equivalent to the Predicate ARROW-LOK Digital Fusion System (K112675). The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, performance and labeling.
<b>Performance Data</b>	Static and dynamic 3-point bending testing (per ASTM 1264-14) confirmed that the Subject device performed as intended.
<b>Conclusion</b>	Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate device, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.