510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

OCT 29 2010

ARROWHEAD FIXATION DEVICE - K100926

Submitted by:	Arrowhead Products LLC 2593 Lake Erma Drive Hampton, GA 30228
Date:	September 18, 2010
Contact Person:	Scott R. Roman, DPM Phone: (404) 583-0248 Fax: (954) 333-2520 Email: romandpm@comcast.net
Proprietary Name:	Arrowhead Fixation Device
Common Name	Intramedullary Bone Fastener
Device Classification Regulation	21 CFR 888.3040 – Class II
Device Product Code and Panel	HTY: Pin, Fixation, Smooth 87 Orthopedics
Device Description	The Arrowhead Fixation Device implant features a three dimensional arrow shape. The implants are available in multiple lengths and in 2 different angles. The implant is manufactured from stainless steel and is designed for single use only.
Intended Use	The Arrowhead is indicated for fixation of osteotomies, arthrodeses and reconstruction in the lesser toes following corrective procedures. It is not intended for use in the spine.
Predicate Devices	newdeal, S.A. K-wire (K022599) Arthrex, Inc. K-wire (K052736) Nexa Orthopedics, Inc. Nexfix Compression Pin (K072710) BioPro Inc., DCS (K963433) Wright Medical Technologies, Inc. PRO-TOE VO Hammertoe (K101165) Merete Medical GMBH PRO TOE Endosorb Small Hammer Toe Pin (K100414)

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Technological Characteristics	The Arrowhead Fixation Device has similar technological characteristics when compared to the predicate devices. In addition, substantial equivalence was shown through Rotational Forces Testing, Pull-out Testing and Four-Point Bend Testing. The testing confirmed that the Arrowhead Fixation Device is at least equivalent to the newdeal K-wire.
Substantial Equivalence Information	The Arrowhead Fixation Device is similar to legally marketed devices including the newdeal K-wire, Arthrex K-wire, Nexfix Compression Pin, BioPro DCS, PRO-TOE VO Hammertoe, and the PRO TOE Endosorb Small Hammer Toe Pin. The Arrowhead Fixation Device has similar indications for use and technological characteristics as these predicate systems. While the Arrowhead Fixation System includes an arrow design at the ends of the device, mechanical testing confirmed that the device is substantially equivalent to the newdeal K-wire. Therefore, the Arrowhead Device System is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Arrow Products, Inc.
c/o Dr. Scott Roman
Podiatrist
2593 Lake Erma Drive
Hampton, Georgia 30228

OCT 29 2010

Re: K100926
Trade/Device Name: Arrowhead Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: HTY
Dated: October 26, 2010
Received: October 27, 2010

Dear Dr. Roman:

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 such 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 9 2010

510(k) Number (if known): K100926

Device Name: Arrowhead Fixation Device

Indications for Use:

The Arrowhead is indicated for fixation of osteotomies, arthrodeses and reconstruction in the lesser toes following corrective procedures. It is not intended for use in the spine.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100926