2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS	
Date Summary Prepared	June 11, 2014
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
Trade Name	**Arthrex PIP Dart**
Common Name	Pin
Product Code -Classification Name ***CFR***	HTY – Pin, Fixation, Smooth 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	*K050259: Arthrex Bio-Pin*
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain FDA clearance for the **Arthrex PIP Dart.**
Device Description	The ***Arthrex PIP Dart*** is an implant with a barbed design that is inserted between the proximal and middle phalanges so the barbs fixate on the phalangeal canal of the toe. The PIP Darts are made of PEEK OPTIMA, offered in straight and 10 degree variations, and range from 2.5mm to 3.0mm in diameter and 25mm to 30mm in length.
Intended Use	The ***Arthrex PIP Dart is*** intended to fix small bony or apical chondral fragments in the foot, ankle, upper extremities, hand, and wrist, where such fragments are not under tension or load-bearing. These devices are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The devices can be used for

	inherently stable intramedullary stabilization of joint arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. This device is also used in inherently stable long bone fractures such as the femur, fibula, tibia, radius and ulna, including the diaphyseal, epiphyseal, and metaphyseal areas.
Substantial Equivalence Summary	The ***Arthrex PIP Dart*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex PIP Dart*** and the predicate are considered minor and do not raise questions concerning safety and effectiveness. The shear testing and pull-out testing data submitted demonstrates that there is no significant difference in mechanical strength between the Arthrex PIP Dart and the predicate. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex PIP Dart*** is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 18, 2014

Arthrex, Inc.
Mr. David L. Rogers
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K141577
Trade/Device Name: Arthrex PIP Dart
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: June 27, 2014
Received: July 3, 2014

Dear Mr. Rogers:

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,

Lori A. Wiggins

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

Enclosure

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-01
Expiration Date: December 31, 201
See PRA Statement on last page.

510(k) Number *(if known)* K141577

Device Name

Arthrex PIP Dart

Indications for Use *(Describe)*

*The **Arthrex PIP Dart** is intended to fix small bony or apical chondral fragments in the foot, ankle, upper extremities, hand, and wrist, where such fragments are not under tension or load-bearing. These devices are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The devices can be used for inherently stable intramedullary stabilization of joint arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. This device is also used in inherently stable long bone fractures such as the femur, fibula, tibia, radius and ulna, including the diaphyseal, epiphyseal, and metaphyseal areas.*

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices