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4 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Nancy Hoft Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1113 Fax: 239/598.5508 Email: nancy.hoft@arthrex.com
Trade Name	Arthrex Meniscal Dart, Arthrex Meniscal Dartstick, Arthrex Chondral Dart
Common Name	Pin, Dart
Product Code - Classification Name	• **HTY**-Pin, fixation, smooth • **MAI**-Fastener, Fixation, Biodegradable, Soft Tissue
Predicate Devices	K983577, Arthrex Meniscal Dart System K991971, Arthrex Chrondral Dart
Device Description and Intended Use	The Arthrex Meniscal Dart, Arthrex Meniscal Dartstick, and Arthrex Chondral Dart are identical to the predicate devices. The Arthrex Meniscal Dart and Arthrex Meniscal Dartstick are intended to be use for the repair of meniscal tears. The Arthrex Chondral Dart is intended to be used for the fixation of small bone fragments. See the Indications for Use statements for specific indications.
Substantial Equivalence Summary	The Arthrex Meniscal Dart, Arthrex Meniscal Dartstick, and Arthrex Chondral Dart are identical to the predicates Arthrex Meniscal Dart System and Arthrex Chondral Dart in which the basic features and intended uses are the same. Any differences between the Arthrex Meniscal Dart, Arthrex Meniscal Dartstick, and Arthrex Chondral Dart in comparison to the cleared devices in K983577 and K991971 are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Arthrex Meniscal Dart, Arthrex Meniscal Dartstick, and Arthrex Chondral Dart are substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2008

Arthrex, Inc.
% Ms. Nancy Hoft
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K082999
Trade/Device Names: Arthrex Menical Dart System
Arthrex Chondral Dart
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HTY
Dated: October 6, 2008
Received: October 8, 2008

Dear Ms. Hoft:

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.

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number: K082999

Device Name: Arthrex Menical Dart System

The Arthrex Meniscal Dart System is intended for the repair of Meniscal tears that would otherwise be considered for standard repair using suture.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use

510(k) Number: K082999

Device Name: Arthrex Chondral Dart

The Chondral Dart is intended for the use in fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following: Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal), osteochondral fragments (talus vault, femoral chondyle) and cancellous fragments (talus).

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K082999