

K991971

AUG 4 2000

510(k) Summary

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
Phone: (941) 643-5553
Fax: (941) 643-6218
Contact: Vernon C. Brown
Manager of Regulatory Affairs (ext. 117)

Trade Name: Arthrex Chondral Dart
Common Name: NA
Classification: Fastener, Fixation, Biodegradable, Hard Tissue

Description:

The Chondral Dart is molded from Poly(L-lactide), has a diameter of 1.3 mm, and is supplied in a length of 18 mm. The device is barbed to facilitate fixation in bone.

Intended Use:

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 condyle) and cancellous fragments (talus).

Substantial Equivalence:

By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

A substantial equivalence comparison is given in Table A. The Arthrex Chondral Dart is as safe and effective as the predicate devices. Furthermore, it does not raise any different questions regarding safety and effectiveness from the predicate device.

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Table A: Substantial Equivalence Comparison

Company	Device	Material	Size(s)	Insertion
Arthrex	Chondral Dart	Poly (L-lactide)	Diameter: 1.3 mm Length: 18 mm	Interference Fit "Pushed" into place
Johnson and Johnson	Orthosorb® Absorbable Pin	Polydioxanone	Diameter: 1.3 & 2.0 mm Length: 40 mm	Interference Fit "Pushed" into place
Synthes (U.S.A.)	Polypin™	Poly(L, DL-lactide)	Diameter: 2.0 mm Length: 35 mm	Interference Fit "Pushed" into place
Bioscience Inc.	Biofix® Pin	Poly(L-lactide)	Diameter: 1.1 - 3.2 mm Length: 10 - 70 mm	Interference Fit "Pushed" into place
Biomet Inc.	Lactosorb® Bone Pin	Poly(lactic acid & Polyglycolic acid copolymer)	Diameter: 2.0 mm Length: 35 mm	Interference Fit "Pushed" into place
Surgical Dynamics™	Bone Pin	Unknown	Unknown	Interference Fit "Pushed" into place



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vernon C. Brown
Manager of Regulatory Affairs and Quality Assurance
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K991971
Trade Name: Arthrex Chondral Dart
Regulatory Class: II
Product Code: HTY
Dated: May 9, 2000
Received: May 9, 2000

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Dianne R. Vodner

CM Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

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 condyle) and cancellous fragments (talus).

James R. Vodmer.

(Division Sign-Off)

Division of General Restorative Devices

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