

510(k) Summary**10/5/98**

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
Phone: (941) 643-5553
Fax: (941) 643-6218
Contact: Scott M. Durlacher
Director of Regulatory Affairs and Quality Assurance (ext. 117)

Trade Name: Arthrex Meniscal Dart System
Common Name: NA
Classification: Fastener, Fixation, Biodegradable, Soft Tissue

Description:

The meniscus aids in load transmission, shock absorption, and joint lubrication, as well as contributing to joint stability. As such, it is desirable to keep the meniscus intact. In the past, a partial meniscectomy was the treatment of choice; however, more recently, instead of removing the damaged or detached meniscal tissue, various suturing techniques have been utilized to repair it. In order for this to be successful, though, the tear must exist in a vascular region ("red-red" and "red-white").

A majority of meniscal tears occur in the posterior horn of the meniscus. Meniscal suturing in this region increases the risk of neurovascular complications, including saphenous and peroneal nerve and popliteal injury. In this case, due to concerns with needle placement, all inside meniscal fixation devices provide a safe alternative.

The meniscal fixation device of choice at the moment is the Bionx Arrow. It has barbs to secure the tissue and a "T" head that rests on top of the meniscus. Studies have shown that the Arrow performs similar to suture depending on the chosen technique, horizontal vs. vertical (Albrecht-Olsen et al., 1997). Although the vertical suture method is superior to using a horizontal method or meniscal fixation device, according to Albrecht-Olsen et al. this technique may be difficult to use when space is limited as is the case for the location of many bucket-handle lesions.

Additional testing was performed comparing the Arthrex Mensical Dart to the Bionx Arrow. Three repair locations were tested, medial posterior, medial anterior and lateral central. There were no significant differences between the Dart and the Arrow for the average pull-out force of all repair locations combined. Furthermore, when comparing the results for the medial posterior location (i.e. the area most commonly associated with meniscal tears), the Dart had the same average pull-out (30 N) as the Arrow and a smaller standard deviation.

With respect to pull-out, all but one Arrow pulled out at the pointed end, whereas the Darts pulled out at both the pointed end and the flat end. This is to be expected considering the fact that the Arrow has a "T" head design. However, since the "T" head sits proud on the meniscus,

there is the increased potential for damage to femoral condyle articular cartilage. In order to eliminate this concern, the Arthrex device does not have a head and is implanted flush with the surface of the meniscus.

Intended Use:

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

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.

The material for the Meniscal Dart, Poly (L,DL-Lactide), has undergone extensive in-vitro and in-vivo testing. Further evaluation of the material was conducted by Claes et. al. (“New bioresorbable pin for the reduction of small bony fragments: design, mechanical properties and in vitro degradation” – Biomaterials, 1996, Vol. 17 No. 16).

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

Table A: Substantial Equivalence Comparison

| Company | Device | Material | Size(s) | Insertion | Pull-Out (overall) | Pull-Out (medial posterior) |
|-----------------------|---------------|-----------------------------|--|------------------|-------------------------------|--|
| Arthrex | Meniscal Dart | Poly (L, DL-lactide) | Diameter: 1.3 mm Length: 10, 12, 14 mm | Impact | 24.9 lbs. | 29.9 lbs. |
| Bionx | Arrow | Poly-L-lactide (SR-PLLA) | Diameter: 1.1 mm Length: 10, 13, 16 mm | Impact | 33.3 lbs. | 30.9 lbs. |
| Innovasive Devices | Clearfix | Poly-L-lactide | Diameter: unknown Length: 10, 11, 13 mm | Screw | unkown | unkown |



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Mr. Vernon Brown
Manager of Regulatory Affairs
Arthrex, Incorporated
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K983577
Trade Name: Arthrex Meniscal Dart System
Regulatory Class: II
Product Code: MAI
Dated: August 4, 1999
Received: August 5, 1999

Dear Mr. Brown:

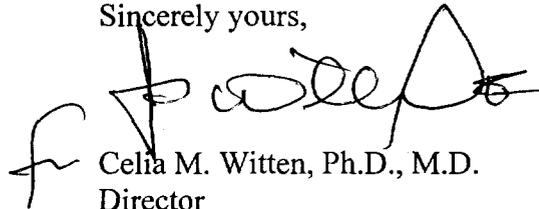
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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 (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

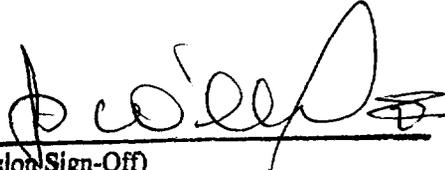
Enclosure



Indications for Use

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
(Per 21 CFR 801.109)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983577

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