

K971358

510(K) SUMMARY FOR ARTHREX, INC.'S BIO-INTERFERENCE SCREW

Submitter's Name, Address, Telephone Number, And Contact Person

Arthrex, Inc.
2885 S. Horseshoe Drive
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JUL - 9 1997

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Date Prepared

April 10, 1997

Name of the Device

The Arthrex Bio-Interference Screw

Common or Usual Name

Bioabsorbable Interference Screw

Classification Name

Bone Fixation Screw

Predicate Devices

1. Arthrex, Inc.'s Bio-Interference Screw
2. Linvatec's BioScrew

Intended Use

The Bio-Interference screw with an expanded indication and the predicate devices are intended to fix a graft to a bone. The Bio-Interference Screw with expanded indications for use and the BioScrew have the same indications for use: to provide interference fixation of bone-tendon-bone and soft tissue grafts in anterior cruciate ligament ("ACL") reconstruction. The devices are indicated for implantation through arthroscopy or arthrotomy.

Principles of Operation

In an ACL reconstruction, the surgeon: (1) creates tibial and femoral tunnels; (2) harvests and prepares a graft; (3) places the graft in the tunnels; and (4) inserts screws between the tunnel wall and graft to hold the graft in place. The ACL reconstruction procedure is similar regardless of whether Linvatec's BioScrew, Arthrex's cleared Bio-Interference Screw, or Arthrex's Bio-Interference Screw with an expanded indication is used. The only difference between the techniques to implant the Bio-Interference Screw with an expanded indication and Linvatec's BioScrew is the method of attaching the driver to the screw during insertion. Moreover, the only differences between the implantation techniques for the cleared Bio-Interference Screw and Bio-Interference Screw with an expanded indication are the preparation of the graft and type of tissue against which the screw is inserted.

During a soft tissue graft ACL reconstruction with Linvatec's BioScrew or Arthrex's Bio-Interference Screw with an expanded indication, the surgeon cores tunnels in the tibia and femur and removes the bone cores. The surgeon then removes a portion of a tendon, such as the hamstring, patella, tendonitis, or gracilis. The surgeon next prepares the soft tissue graft by folding the graft in half and, with a suture, whip stitching each end of the tendon for a distance of 3 cm; the whip stitching helps prevent the graft from wrapping up when the screw is introduced. After graft preparation, the surgeon places one end of the graft in the tibial tunnel and the other end in the femur tunnel. To fix the graft ends in the tunnels, the surgeon inserts the screws using a driver supplied by the screw manufacturer; the screws fit between the soft tissue grafts and tunnel walls. Both the Bio-Interference Screw and BioScrew are inserted through a sheath accessory that protects the graft from damage by the screw threads during insertion.

The principal difference in the insertion techniques of Linvatec's BioScrew and Arthrex's Bio-Interference Screw with an expanded indication is the method of attaching the driver to the screw during insertion. Whereas Arthrex's driver has a hexagonal socket that fits over Arthrex's hexagonal-headed screw, Linvatec's driver has three lobes that fit into Linvatec's screw. This difference does not raise any new issues of safety or effectiveness because use of a hexagonal-headed screw has a minor impact on how the screw is deployed: Arthrex and Linvatec's drivers are placed against the screw and torque is applied to the screw by the surgeon through the driver.

Technological Characteristics

There are no technological differences between the cleared Bio-Interference Screw and the Bio-Interference Screw with the expanded indication except for a slight radius on the hexagonal head and a slight taper on the tip; these modifications are very minor. The Bio-Interference Screw also has technological characters very similar to the BioScrew. For instance, they are made of bioabsorbable PLA. They have the same diameters and very similar thread

lengths, overall length, number of threads, and thread pitch. The minor difference in length, 2 mm, between Linvatec's 25 mm screw and Arthrex's 23 mm screw does not raise any new issues of safety or effectiveness because the magnitude of the difference is small. Furthermore, the length of the Bio-Interference Screw with an expanded indication is within the range of the lengths of the cleared BioScrew.

The cleared Bio-Interference Screw and the Bio-Interference Screw with an expanded indication are implanted with the same accessories: a screw sheath, driver, guide wire, dilator, notcher, tap, and remover. In addition, the Bio-Interference Screw with the expanded indication and the BioScrew also are implanted with similar accessories: screw sheaths, guide wires, taps, notchers, and drivers. The BioScrew's accessories also are made of materials such as stainless steel and aluminum.

The Bio-Interference Screw has the same intended use and indications for use as the BioScrew. In addition they both have very similar principles of operation and technological characteristics. Furthermore, except for the radius and taper modification, the Bio-Interference Screw has not been modified since it was cleared by FDA in a previous 510(k) notice. Thus, the Bio-Interference Screw is substantially equivalent to the BioScrew for interference fixation of bone-tendon-bone and soft tissue grafts in ACL reconstruction.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jonathan S. Kahan
Hogan and Hartson L.L.P.
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JUL - 9 1997

Re: K971358
Trade Name: Bio-Interference Screw
Regulatory Class: II
Product Code: MAI
Dated: April 11, 1997
Received: April 11, 1997

Dear Mr. Kahan:

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 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.

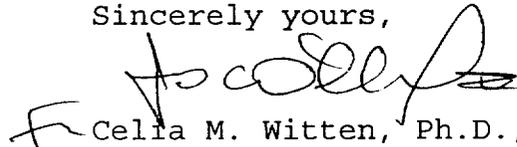
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,


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

510(k) Number (if known): _____

Device Name: Bio-Interference Screw

Indications For Use:

To provide interference fixation of bone-tendon-bone and soft tissue grafts in ACL reconstruction through arthroscopy or arthrotomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12971358

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____