

JUN 10 1998

510(k) Summary

K973812

9/26/97

Company: Arthrex, Inc.
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Contact: Scott M. Durlacher
Director of Regulatory Affairs and Quality Assurance (ext. 117)

Trade Name: Arthrex Opening Wedge Osteotomy System
Common Name: Bone Plate and Accessories
Classification: Plate, Fixation, Bone (per 21 CFR 888.3030)

Description:

There are two schools of thought regarding osteotomy methods: the closing wedge method, and the opening wedge method, in the closing wedge method, removal of a bone wedge creates an angled gap in the bone. Part of the bone is left as a hinge at the apex of the angle. The hinge allows the gap to narrow and the bone material on either side of the closed gap joins together.

In the opening wedge method, a cut is made across the bone. Part of the bone is left as a hinge, as in the closing wedge method. In contrast to the closing wedge method, however, the hinge allows the cut gap to open. The open wedge is filled with graft material.

The two methods are performed on opposite sides of the bone to give equivalent results. For example, when a given deformity would be corrected by performing the opening-wedge procedure on the medial side of a bone, an equivalent closing-wedge correction would be performed laterally.

The closing wedge method is the current standard, although several disadvantages are associated with the technique. The most significant disadvantages of the closing wedge method are: (i) disruption of the tibial-femoral joint; (ii) possible damage to neurovascular structures; and, (iii) disruption of the medial cortex, resulting in instability and nonunion between the upper and lower bone because of possible soft tissue interference. It is also difficult to compute the correct amount of bone to remove, and, therefore, several extra cuts may be required.

The opening wedge technique avoids or limits many of the disadvantages associated with the closing wedge-method. Additionally, the medial, open-wedge HTO has the following advantages over the closed, lateral-wedge HTO: (i) speed; (ii) simplicity; (iii) ability to quickly change angle at any time during the procedure; and (iv) no fibular osteotomy is required. Nevertheless, only a few surgeons are currently using the opening wedge procedure. This is most likely due to a lack of functional, easy to use instrumentation.

The Arthrex Opening Wedge Osteotomy System overcomes the disadvantages of the prior art and fulfills the above-described need by providing a bone plate system for performing the opening wedge osteotomy technique. The bone plate system of the present invention includes the following basic components: a guide system, osteotomes, a forked-wedge tool for opening the wedge, and a set of bone plates for maintaining the wedge opening.

The osteotomy plates are made of surgical grade stainless steel, the biocompatibility of which has been well documented.

Intended Use:

The Arthrex Opening Wedge Osteotomy System are intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial or Distal Femoral opening wedge osteotomies.

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 primary differences between the Arthrex and Intermedics bone plates are as follows:

	Intermedics	Arthrex
Configuration	"L" shaped plates	"T" shaped and "T" shaped plates
Metal Spacer	No	Yes
Material	Titanium Alloy	Surgical Grade Stainless Steel

The configuration of any bone plate should ideally provide both axial and torsional stability. Since each of these designs provides fixation in more than one plane, such stability is guaranteed. The Intermedics technique calls out for the opening resulting from an opening wedge osteotomy to be filled with a combination of cancellous bone and wedges of bone from the Iliac Crest. The Arthrex technique also calls out for the use of wedges of bone; however, the Arthrex plate also has a metal spacer to provide further support. Although the material for the two plates differs, both have proven track records as acceptable implant materials. Surgical Grade Stainless Steel has been and still is commonly used in a number of fixation devices. None of the aforementioned differences make the Arthrex plates any less safe and effective than the Intermedics plates. Furthermore, they do not raise any different questions regarding safety and effectiveness from the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott M. Durlacher
Director of Regulatory Affairs
and Quality Assurance
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K973812
Trade Name: Arthrex Opening Wedge Osteotomy System
Regulatory Class: II
Product Code: HRS
Dated: May 19, 1998
Received: May 21, 1998

Dear Mr. Durlacher:

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.

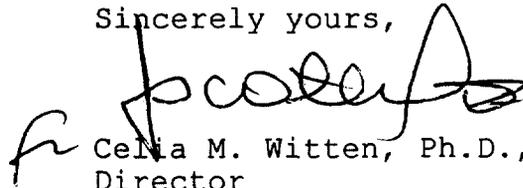
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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



Indications for Use

The **Arthrex Opening Wedge Osteotomy System** is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial or Distal Femoral opening wedge osteotomies.

Prescription Use X
(Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

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