

SEP 28 2005

K052614

## VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS Arthrex Low Profile Plate and Screw System

**NAME OF SPONSOR:** Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945

**510(K) CONTACT:** Sally Foust, RAC  
Regulatory Affairs Project Manager  
Telephone: (239) 643-5553 extension 1251  
FAX: (239) 598-5539

**TRADE NAME:** Arthrex Low Profile Plate and Screw System  
**COMMON NAME:** Plate, fixation, bone  
Screw, fixation, bone

**CLASSIFICATION /  
PRODUCT CODE** 21 CFR 888.3030 / HRS  
Single/multiple component metallic bone fixation  
appliances and accessories  
21 CFR 888.3040 / HWC  
Fastener, Fixation, Nondegradable, Soft Tissue  
Smooth or threaded metallic bone fixation  
fastener

**PREDICATE DEVICES:**  
K040907 Arthrex Small Fragment Plates and Screws

#### **DEVICE DESCRIPTION AND INTENDED USE:**

The Arthrex Low Profile Plate and Screw System consists of plates and screws. The plate is an L-shaped plate with four holes for insertion of screws for fixation. The plate is available in opening and closing wedge design, in various lengths, in both left and right configurations. The Arthrex screw is a cortical, headed, self-tapping screw available in one diameter, in numerous length options.

The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies for Hallux Valgus.

#### **SUBSTANTIAL EQUIVALENCE SUMMARY**

The Arthrex Low Profile Plate and Screw System is substantially equivalent to the predicate device where basic features and intended uses are the same. Any differences between the Low Profile Plate and Screw System and the predicate device are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Low Profile Plate and Screw System is substantially equivalent to the currently marketed predicate device.



SEP 28 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sally Foust, RAC  
Regulatory Affairs Project Manager  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945

Re: K052614

Trade/Device Name: Arthrex Low Profile Plate and Screw System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances  
and accessories

Regulatory Class: II  
Product Code: HRS, HWC  
Dated: September 21, 2005  
Received: September 23, 2005

Dear Ms. Foust:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

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

Enclosure

III. INDICATIONS FOR USE FORM

510(k) Number (if known): \_\_\_\_\_

Device Name: Arthrex Low Profile Plate and Screw System

Indications for Use:

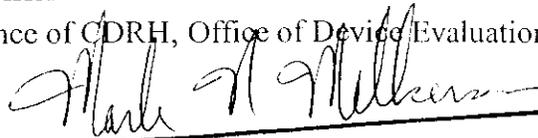
The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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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   K052619