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K041965
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Small Fragment Plates and Screws

NAME OF SPONSOR:

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Sr. Regulatory Affairs Specialist
Telephone: (239) 643-5553 extension

1251

FAX: (239) 598-5539

TRADE NAME:
Screws

Arthrex Humeral Fracture Plates &

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:

K011334 Synthes Curved Reconstruction Plate
K031178 Synthes 3.5mm Broad LCP & 4.5mm CLP Distal Humerus Plate
K032559 Synthes 4.0mm Titanium Locking Screws
K011170 Synthes 2.7mm LC-DCP, 3.5mm Profile Plate
K983853 DePuy ACE TiMAX™ Meta Plate

DEVICE DESCRIPTION AND INTENDED USE:

The Arthrex Humeral Fracture Plate is designed as a spoon shaped plate to anatomically fit on the lateral proximal aspect of the humerus. The plate is available in two size configurations, standard and long. Spherical holes with bushings allow for angular locking of the screws in the plate. Smaller holes in the center of the plate allow for temporary fixation during surgery with K-wires. Peripheral holes allow re-approximation of soft tissue with suture, such as FiberWire®. The screws are available in various lengths in two design options, cortical and cancellous. The cortical screws are 3.5 mm in diameter and the cancellous screws are 4.0 mm in diameter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Sally Foust, RAC
Senior Regulatory Affairs Specialist
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K041965
Trade/Device Name: Arthrex Humeral Fracture Plates and Screws
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS, HWC
Dated: July 17, 2004
Received: July 21, 2004

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 (301) 594-4659. 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,

for Mark N. Melkerson

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

510(k) Number (if known): K041965

Device Name: Arthrex Humeral Fracture Plates and Screws

Indications (from labeling):

The Arthrex Humeral Fracture Plates and Screws are intended to provide internal fixation of proximal fractures of the humerus.

Prescription Use ___X___ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041965