MAY 1 2 2004

K040381

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex HATriC™

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: HATriC™
COMMON NAME: Bone Void Filler
CLASSIFICATION: Resorbable Calcium Salt Bone Void Filler Device
21 CFR 888.3045

DEVICE PRODUCT CODE: MQV

DEVICE DESCRIPTION AND INTENDED USE:

HATriC™ is a bone void filler or bone graft substitute. HATriC™ is designed as a block of two-phase ceramic calcium phosphate consisting of 60% hydroxyapatite and 40% ß-tricalcium phosphate in a wedge configuration. HATriC™presents as a multidirectional interconnected porosity structure, similar to that of human cancellous bone. The HATriC™ implant resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues.

The intended use for HATriC™ is that of a bone void filler or bone graft substitute in bony voids or gaps which are not intrinsic to the stability of the bony structure (i.e. extremities, pelvis, or spine). These bony voids and gaps may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. HATriC™ may be used as a bone graft substitute for autograft or allograft when these grafts are undesirable or unavailable.

When used for posterolateral fusions, the HATriC™ must be used with autograft bone material and the ratio of autograft bone material to HATriC™ must be in the range of 1.25cm^3 to 2.4cm^3 of autograft bone to 1cm^3 of HATriC™.

HATriC™ is a bone void filler or bone graft substitute that resorbs and is replaced with bone during the healing process. HATriC™ is not intended to be a load-bearing device. Therefore rigid fixation techniques may often be recommended.

In addition, when used with Arthrex Opening Osteotomy Systems' or substantially equivalent systems' plates and screws, HATriC™ is intended to be used as a bone void filler or bone graft substitute in femoral or tibial osteotomies. HATriC™ is to be used in association with adequate post-operative immobilization.

SUBSTANTIALLY EQUIVALENCE

HATriC™ is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the HATriC™ device are considered minor and do not raise questions concerning safety and effectiveness. Based on clinical data and mechanical rationale submitted, when used with Arthrex Opening Osteotomy Systems' or substantially equivalent systems' plates and screws, HATriC™ is intended to be used as a bone void filler or bone graft substitute in femoral or tibial osteotomies, which falls within the general indications of the predicate/marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2 2004

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

Re: K040381
Trade/Device Name: HATriC™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: February 16, 2004
Received: February 18, 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 Milhorn

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): K040381

Device Name: HATriC™

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milleson

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

510(k) Number K040381