K030096

MAR 1 8 2003

PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Arthroscopes

NAME OF SPONSOR:

Arthrex, Inc.
2885 S. Horseshoe Drive
Naples, Florida 34104

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
Telephone: (239) 643-5553 extension 1251
FAX: (239) 430-3494

TRADE NAME: Arthrex Arthroscopes

COMMON NAME: Arthroscope

CLASSIFICATION:

Arthroscope
21 CFR 888.1100

DEVICE PRODUCT CODE: HRX

DEVICE DESCRIPTION AND INTENDED USE:
Arthrex Arthroscopes are rigid, fixed arthroscopes with a wide-angle view. Arthrex Arthroscopes have surgical stainless steel shafts and lens housings for durability and are available with a 30 or 70 degree angle view. The optical components are sealed to provide a durable focusing mechanism. The arthroscopes may be attached to a video camera and are available in various sizes, diameters and lengths, to provide for differences in arthroscopic surgical site and surgeon preference.

The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

SAFETY AND EFFECTIVENESS
The Arthrex, Inc. Arthroscopes are similar to the predicate devices in design, materials, and intended use and as such are considered by Arthrex, Inc. to be substantially equivalent to devices currently available in U.S. distribution. The expansion of the indications of the Arthrex, Inc. Arthroscopes to include elbow and hip, those of the Smith & Nephew predicate device, does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2003

Ms. Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
2885 S. Horsehoe Drive
Naples, Florida 34104

Re: K030096
Trade/Device Name: Arthrex Arthroscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscopes and accessories
Regulatory Class: II
Product Code: HRX
Dated: January 9, 2003
Received: January 10, 2003

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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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 Miriam C. Provost

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) K030096

INDICATIONS FOR USE:

The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

Hip diagnostic procedures may include:
Staging of avascular necrosis
Chondral injuries
Joint sepsis
Synovial chondromatosis
Unresolved hip pain
Labral tears

Concurrence of CDRH, Office of Device Evaluation

Prescription Use __X__ OR Over-The-Counter Use

(Per 21 CFR 801.109)

Miriam C. Provost

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

510(k) Number K030096

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