DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JAN 25 1994

Mr. Leonard E. Baltz, Jr.
Engineering Consultant
Arthrex, Inc.
3050 North Horseshoe Drive, Suite 200
Naples, Florida 33942

Re: K932699
Arthrex AR-8200 Shaver System
Regulatory Class: I
Dated: January 5, 1994
Received: January 6, 1994

Dear Mr. Baltz:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

OD

CDRH Premarket Notification

U.S. Food and Drug Administration - Center for Devices and Radiol

Other | 510(K) | Listing | MAUDE | PMA | Classification

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Device Classification Name	INSTRUMENT, SURGICAL, ORTHOPEDIC, AC-POWERED AND ACCESSORY/ATTACHMENT
510(k) Number	K932699
Device Name	ARTHREX AR-8200 SHAVER SYSTEM
Applicant	ARTHREX, INC. 3050 NORTH HORSESHOE DR. SUITE 200 NAPLES,FL33942
Contact	BALTZ, JR
Product Code	HWE
Date Received	06/03/1993
Decision Date	01/25/1994
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Statement/purged 510(k)
Type	Traditional
Reviewed by Third Party	No

(Database Updated July 6, 2001)

Accessibility

Arthrex, Inc.

K932699

Indications for Use

The **Arthrex AR-8200 Shaver System** is a motorized suction/cutting device used for the resection and aspiration of soft tissue, cartilage and bone during arthroscopic surgical procedures.

Mariela Cabarcas
Coordinator of Regulatory Affairs
Signed off 6/8/2004