DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

APR 15 1994

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

Re: K921119
Arthrex Arthroscope
Regulatory Class: II
Dated: December 27, 1993
Received: December 28, 1993

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-326) 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,

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

510(k) Premarket Notification Database

Device Classification Name	Arthroscope
510(K) Number	K921119
Regulation Number	888.1100
Device Name	ARTHREX ARTHROSCOPE
Applicant	ARTHREX, INC. 3050 North Horseshoe Dr. Suite 200 Naples, FL 33942
Contact	Don Grafton
Product Code	HRX
Date Received	03/09/1992
Decision Date	04/15/1994
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Statement/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No

Database Updated 5/7/200

Arthrex, Inc.

K921119

Indications for Use

The **Arthrex Arthroscope** these scopes are intended for use in ACL/PCL and basic reconstruction surgery of knee, shoulder, wrist, ankle, and TMJ.

Mariela Cabarcas
Coordinator of Regulatory Affairs
Signed off 6/9/2004