DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

FEB 9 1993

Mr. Don Grafton
V.P. Engineering
Arthrex Inc.
3050 North Horseshoe Drive
Suite 168
Naples, Florida 33942

Re: K915424
Arthrex Cannulated Interference Screw
Regulatory Class: II
Dated: July 29, 1992
Received: July 30, 1992

Dear Mr. Grafton:

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 Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. 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.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Device Classification Name	SCREW, FIXATION, BONE
Regulation Number	888.3040
510(k) Number	K915424
Device Name	ARTHREX CANNULATED INTERFERENCE SCRE
Applicant	ARTHREX, INC. 3050 NORTH HORSESHOE DR. SUITE 200 NAPLES, FL 33942
Contact	DON GRAFTON
Product Code	HWC
Date Received	12/02/1991
Decision Date	02/09/1993
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 March 5, 2002)

Accessibility