K023986

DEC 17 2002

510(k) Summary

510(k) Number:

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Dr., Naples, FL 34104
Telephone: (239) 643-5553
Facsimile: (239) 430-3494
Contact: Ann Waterhouse

Trade Name: Arthrex OPES Electrodes and Accessories
Common Name: High Frequency Devices and Accessories
Product Code: GEI

Description:

The Arthrex electrosurgical cutting and coagulation devices and accessories are monopolar in structure, allowing for a range of surgical repairs. The electrodes are sold sterile, single use in a pouch/pouch configuration.

Indications for Use:

The Arthrex electrosurgical ablation devices and accessories are intended for use in resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels and tissue in general, arthroscopic, and orthopedic procedures. Specifically, these devices and their accessories will be used for general surgeries, and open and arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, and ankle.

Substantial Equivalence:

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Arthrex product line and the predicate devices with similar indications do not raise any questions regarding the safety and effectiveness. Furthermore, the device and accessories are well characterized and have been used in surgical applications with similar indications. The devices, as designed, are as safe and effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

TUV Product Service
Mark Job
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K023986
Trade/Device Name: Arthrex Opes Electrodes and Accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 29, 2002
Received: December 2, 2002

Dear Mr. Job:

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). 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,

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023986

Device Name: Arthrex OPES Electrodes and Accessories

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Option Format 3-10-98)

Prescription use ✓

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

510(k) Number K023986