JUL 23 1997

K971532

X. 510(k) Summary

A. *Name of Device*

Trade name:	ArthroCare Electrosurgery System
Common name:	Electrosurgical System
Classification name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

B. *Predicate devices*

Device	Premarket Notification
ArthroCare Arthroscopic Electrosurgery System 970	K943450, 03/10/95
ArthroCare Bipolar Loop Electrosurgery System	K955531, 02/21/96
ArthroCare Urologic Multi-electrode Electrosurgery System	K961069, 05/28/96
ArthroCare Dental Wand System	K962445, 07/30/96
ArthroCare Electrosurgery System 980	K963123, 10/08/96
ArthroCare General Dermatology Electrosurgery System	K964849, 04/14/97
Conmed Hyfrecator	K800617, 05/02/80 K850668, 05/20/85

C. *Device description*

The ArthroCare Electrosurgery System is comprised of three components: the Probe, the Probe Cable, and an electrosurgical generator called the Controller. The Probe Cable connects the Controller to the Probe. The Probe is provided in a variety of models with the distal tip of the probe as straight or bent at angles up to 90 degrees. The distal tip may be configured with multi-electrodes or as a loop electrode. The Probe is supplied sterile and intended for single patient use. The Probe Cable is designed for repeat sterilization by either ethylene oxide gas or steam autoclaving methods, as selected by the user. The Controller is a high

frequency electronic instrument. There is no software utilized in the operation of the Controller.

The ArthroCare Electrosurgery System is bipolar, incorporating a return electrode on the shaft of the device. This means that a return pad is not required for operation. The return energy in a bipolar device with an integral return electrode does not penetrate the tissue as in a monopolar device. In a monopolar device, the energy passes through the patient's body to reach the return pad.

D. Intended use

The ArthroCare Electrosurgery System is intended for use in general surgical procedures to remove soft tissue and to control bleeding.

E. Technological characteristics

The technological characteristics of the ArthroCare Electrosurgery System are identical to those of the predicate ArthroCare devices, as well as the devices distributed by other manufacturers. These devices are equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

F. Summary

By virtue of design, materials, function and intended use, the ArthroCare Electrosurgery System is substantially equivalent to devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cheryl L. Shea
Director-Regulatory and Clinical Affairs
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086

JUL 23 1997

Re: K971532
Trade Name: ArthroCare Electrosurgery System
Regulatory Class: II
Product Code: GEI
Dated: April 25, 1997
Received: April 28, 1997

Dear Ms. Shea:

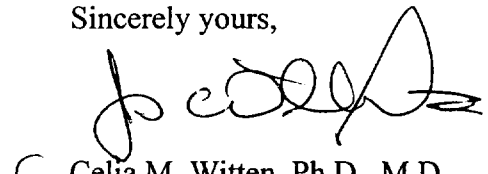
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (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. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

Indications Statement

Device Name: ArthroCare Electrosurgery System
510(k) Number: K971532

Indications for use:

The ArthroCare Electrosurgery System is indicated for soft tissue resection and ablation and coagulation of blood vessels during general surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971532

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)