

X. 510(k) Summary

JAN - 9 1998

K973478

A. Name of Device

Trade name: AccENT Head and Neck Electrosurgery System
Common name: Electrosurgical Unit and Accessories
Classification name: Electrosurgical Cutting and Coagulation Device
(21 CFR 878.4400)

B. Predicate devices

<u>Device</u>	<u>Premarket Notification</u>
ArthroCare Arthroscopic Electrosurgery System	K943450, 03/10/95
ArthroCare Arthroscopic Electrosurgery System 980 (Model 2000)	K963123, 10/08/96
ArthroCare Dental Electrosurgery System	K962445, 07/30/96
ArthroCare General Dermatology Electrosurgery System	K964849, 04/14/97
Stryker Hummer II MicroDebrider System	K952681, 07/20/95
Valleylab Force 2 Electrosurgical Generator	K921884, 12/92
Coherent Medical Versapulse Laser System	K914136
Sharplan CO2 Surgical Laser	K933362

C. Device description

The AccENT Head and Neck Electrosurgery System is comprised of three components: the AccENT Wand, the AccENT Cable, and an electrosurgical generator called the Controller. The Cable connects the Controller to the Wand. The Wand is provided in a variety of models, ranging in diameters from 1.5 mm to 4.5 mm. The Wand offset and distal tip angles range from 0 to 90 degrees. The AccENT wand shaft is configured as straight or offset to allow for better access to the treatment area. The distal tip is configured with multi-electrodes. The Wand is supplied sterile and intended for single patient use. The 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 AccENT Head and Neck 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 AccENT Head and Neck Electrosurgery System is intended for ablation and coagulation of soft tissue in otolaryngological (ENT) surgery including head, neck, oral, and sinus surgery.

E. Technological characteristics

The technological characteristics of the AccENT Head and Neck Electrosurgery System are the same as those of the ArthroCare Arthroscopic, Dental, and General Dermatology Systems. 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 AccENT Head and Neck Electrosurgery System is substantially equivalent to devices currently marketed in the United States.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 1998

Mr. Mark Smutka
Director, Regulatory Affairs and Quality Assurance
Arthrocare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086

Re: K973478
Trade Name: AccENT Head & Neck Electrosurgery System
Regulatory Class: II
Product Code: GEI
Dated: December 11, 1997
Received: December 15, 1997

Dear Mr. Smutka:

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.

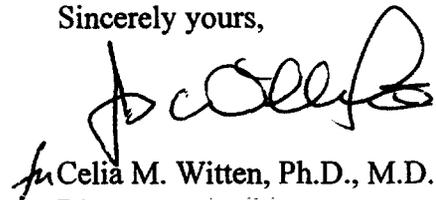
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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: AccENT Head and Neck Electrosurgery System

510(k) Number: K973478

Indications for use:

The AccENT Head and Neck Electrosurgery System is indicated for ablation and coagulation of soft tissue in otolaryngological (ENT) surgery including head, neck, oral, and sinus surgery.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K973478

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____