AUG 20 1998 K981870

X. 510(k) Summary

A. Name of Device

Trade name:	Visage Cosmetic Surgery System
Common name:	Electrosurgical Unit and Accessories
Classification name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

B. Predicate devices

Device	Premarket Notification
ArthroCare Dermal Electrosurgery System	K964849, 04/14/97
ArthroCare Arthroscopic Electrosurgery System (System 2000)	K963123, 10/08/96
ArthroCare Sinus Electrosurgery System (System 2000)	K973478, 1/9/98
ConMed Hyfrecator Plus	K800617, 05/02/80

C. Device description

The Visage Cosmetic Surgery System is shown in Figure 1 (Figures Section), and includes three components. The components are the Handpiece and Cable unit, Handpiece Tip, and the Controller. The Handpiece Tip attaches to the distal end of the Handpiece and Cable unit. The proximal end of the Handpiece and Cable unit connects to the Controller.

The Handpiece Tip is provided in a variety of electrode configurations. The distal tip of the Handpiece is configured with single electrodes or in loop, sheet, or wire form. The Handpiece Tip is supplied sterile and intended for single patient use. The Handpiece and Cable unit are designed for repeat sterilization by steam autoclave. The Controller is a high frequency electronic instrument. There is no software utilized in the operation of the Controller.

The Visage Cosmetic Surgery System is designed for use in general dermatologic surgery for soft tissue resection/removal, and hemostasis/coagulation in procedures using conductive solutions such as saline or Ringer's Lactate as an irrigant. Tissue is removed by ablation and hemostasis is performed by coagulation of tissue.

The Visage Cosmetic Surgery 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 Visage Cosmetic Surgery System is intended for use in general dermatologic surgery for soft tissue resection/removal, and hemostasis/coagulation in procedures using conductive solutions such as saline or Ringer's Lactate as an irrigant.

E. Technological characteristics

The technological characteristics of the Visage Cosmetic Surgery System are the same as those of the ArthroCare Dermal Electrosurgery System, as well as the ArthroCare Arthroscopic Systems and the ConMed Hyfrecator Plus. These devices are equivalent in terms of materials, principle of operation and sterilization.

F. Summary

By virtue of design, principle of operation, materials and intended use, we believe the Visage Cosmetic Surgery System is substantially equivalent to devices currently marketed in the United States. We believe that the Visage Cosmetic Surgery System, which is intended for use in general dermatologic surgery for soft tissue resection/removal, and hemostasis/coagulation does not raise any new issues of safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1998

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

Re: K981870
Trade Name: Visage Cosmetic Surgery System
Regulatory Class: II
Product Code: GEI
Dated: May 26, 1998
Received: May 28, 1998

Dear Mr. Smutka:

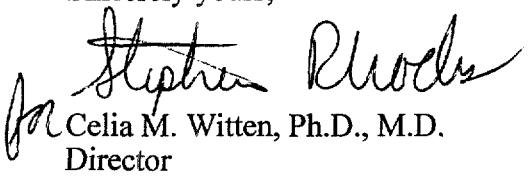
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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

Indications Statement

Device Name: Visage Cosmetic Surgery System
510(k) Number: K981870

Indications for use:

The Visage Cosmetic Surgery System is a bipolar high frequency electrosurgical device intended for general dermatologic surgery for soft tissue resection/removal, and hemostasis/coagulation in procedures using conductive solutions such as saline or Ringer's Lactate as an irrigant.

(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 K981870

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