

MAR 20 2006

K9921P0

**510(k) Summary of
Safety and Effectiveness
ArthroCare, Corporation
Visage™ Cosmetic Surgery System**

General Information

Manufacturer: ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086-2916

Establishment Registration Number: 2951580

Contact Person: Bruce Prothro, Vice President Regulatory
Affairs and Quality Assurance

Date Prepared: June 25, 1999

Device Description

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (21 CFR 878.4400)

Trade Name: Visage™ Cosmetic Surgery System

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

Visage Cosmetic Surgery System K981870
ArthroCare Dermal Electrosurgery System K964849

Establishment of equivalence is based on similarities of intended use, materials, and principle of operations. Additionally, there have been no substantial changes in materials, technology or performance to the Visage Cosmetic Surgery System cleared under 510(k) K981870 and Visage Cosmetic Surgery System presented in this premarket notification.

Intended Use

The Visage Cosmetic Surgery System is a bipolar high frequency electrosurgical device intended for general dermatologic surgery that may include skin resurfacing for the

treatment of wrinkles, rhytids, and furrows, as well as soft tissue resection/removal and hemostasis/coagulation. It is intended to be used in procedures using conductive solutions such as normal saline.

Product Description

The Visage Cosmetic Surgery System is a bipolar, high frequency electrosurgical system designed for use in general dermatologic procedures where ablation and coagulation of soft tissue is desired. The System consists of three components: an electrosurgical generator called the Controller, the disposable Handpiece Tip, and the reusable Handpiece and Cable Unit. The Controller utilizes radio frequency (RF) energy as a power source. RF energy is delivered to the patient via the Handpiece and Cable unit and the Handpiece Tip. The Handpiece and Cable unit is designed to attach to the Controller and Handpiece Tip for patient treatment. The single use, sterile, Handpiece Tip is the patient contacting component of the System. The Handpiece Tip configuration ranges from single to multiple electrodes incorporating straight, screen, loop, and sheet shaped electrodes. The Visage Cosmetic Surgery System uses bipolar technology in the design of the Handpiece Tip eliminating the need for a patient contacting dispersive pad used in monopolar devices.

Substantial Equivalence

This 510(k) notification is for the expansion of the current indications to include skin resurfacing for the treatment of wrinkles, rhytids, and furrows. The Visage Cosmetic Surgery System has not been significantly modified in either technology, principles of operation, or materials since the 510(k) approval of the predicate Visage Cosmetic Surgery System on August 20, 1998 (K981870). The Visage Cosmetic Surgery System is a modification to the initial System, ArthroCare Dermal Electrosurgery System, which was cleared via K964849 on April 14, 1997.

Summary of Safety and Effectiveness

The safety and effectiveness of the Visage Cosmetic Surgery System for skin resurfacing for the treatment of wrinkles, rhytids, and furrows was evaluated in accordance with an approved Investigational Device Exemption (IDE), No. G970168, "ArthroCare Dermal Electrosurgery System for Skin Resurfacing Clinical Study." The Visage Cosmetic Surgery System was found to be both safe and effective for skin resurfacing for the treatment of wrinkles, rhytids, and furrows.



MAR 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce Prothro
Vice President, Regulatory Affairs and
Quality Assurance
ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086-2916

Re: K992180
Trade Name: Visage Cosmetic Surgery System
Regulatory Class: II
Product Code: GEI
Dated: February 11, 2000
Received: February 14, 2000

Dear Mr. Prothro:

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.

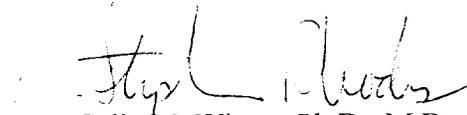
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Bruce Prothro

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: Visage Cosmetic Surgery System
510(k) Number: K992180

Indications for use:

The Visage Cosmetic Surgery System is a bipolar high frequency electrosurgical device intended for general dermatologic surgery that may include skin resurfacing for the treatment of wrinkles, rhytids, and furrows, as well as soft tissue resection/removal and hemostasis/coagulation. It is intended to be used in procedures using conductive solutions such as normal saline.

(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 K992180

Prescription Use
(Per 21 CFR 801.109)

X

OR

Over-the-Counter Use _____