

OCT 14 1999

510K SUMMARY

K992764

Submitted By: ERBE-USA
2225 Northwest Parkway
Suite 105
Marietta, GA 30067

Tel: 770-955-4400
Fax: 770-955-2577

Contact Person: Scott Cundy

Date Prepared: August 16, 1999

Device Name: Common Name: Argon Plasma Coagulation (APC) Raspatory Handle and Tip for use with HF current ERBOTOM ICC Series Electrosurgery Systems and APC devices

Trade Name: ERBE APC Raspatory Handle and Tip

Proprietary Name: ERBE APC Raspatory Handle and Tip

Classification Name: Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)

Product Code: 79GEI

Substantially Equivalent Devices:

The ERBE APC Raspatory Handle and Tip are substantially equivalent to the following legally marketed devices: Beacon Laboratories' Argon Beam Laparoscopic Electrode (K902996) and Valleylab's Curved Spatula Tip Electrode (K904560).

Intended Uses:

The ERBE APC Raspatory Handle and Tip's intended use is for the APC cutting and coagulation. The ERBE APC Raspatory Handle and Tip is used with the ERBOTOM ICC Series Electrosurgery Systems and Argon Plasma Coagulation devices (K963189). The Beacon Laboratories Argon Beam Laparoscopic Electrode also uses argon beam for coagulation, whereas the Valleylab Curved Spatula Tip Electrode uses general electrosurgical current for cutting and coagulation. All three devices target electrosurgical patients.

510K SUMMARY

Device Description:

The ERBE APC Raspatory Handle and Tip and the two substantially equivalent devices meet the AAMI/ANSI HF-18 standard. The ERBE APC Raspatory Handle and Tip is made of a zytel shaft and a ceramic tip. Beacon Laboratories' Argon Beam Laparoscopic Electrode also uses a similar plastic shaft and a ceramic tip. The ERBE APC Raspatory Handle and Tip has a curved spatula-like configuration, which is substantially equivalent to Valleylab's Curved Spatula Tip Electrode. The Valleylab Curved Spatula Tip Electrode uses a similar plastic for the shaft, but uses a steel tip. ERBE has extensive experience in using ceramic tips for APC Applicators; ERBE APC Probes (K963189). The ERBE APC Raspatory Handle and Tip assembly's overall length is 8.5 inches. ERBE APC Raspatory Handle and Tip are two separate components that can be changed/replaced as required. The ERBE APC Raspatory Tip possesses three openings on the concave side of the palatine arch. The argon flows out of the middle opening of the raspatory tip while the side openings suction secretions and possible smoke plume.

ERBE APC Raspatory Handle and Tip is provided non-sterile and are reusable using steam sterilization, whereas the other devices are provided sterile (via Ethylene Oxide and Gamma Radiation) and are disposable. ERBE USA has conducted a sterilization validation per EN45001 to define and support the reesterilization. ERBE's APC Raspatory Handle and Tip and Beacon's electrode use argon gas, whereas the Valleylab uses conventional electrosurgical current.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott Cundy
Regulatory Affairs/Quality Assurance Manager
ERBE USA, Inc.
2225 Northwest Parkway
Suite 105
Marietta, Georgia 30067

Re: K992764
Trade Name: ERBE APC Raspatory Handle and Tip
Regulatory Class: II
Product Code: GEI
Dated: August 16, 1999
Received: August 17, 1999

Dear Mr. Cundy:

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.

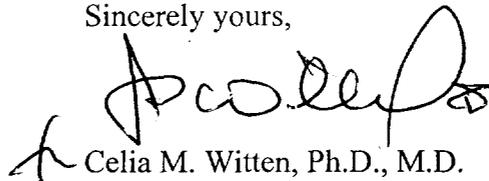
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

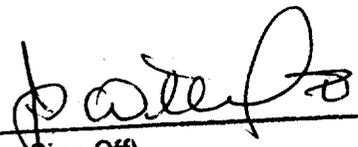
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K 99 2764

- Argon Plasma Cutting and Coagulation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 992764

Prescription Use X
(Per 21 CFR 801.109)