

OCT 14 1999

K992769

510(k) SUMMARY

**ERBE**

USA INCORPORATED  
Electrosurgical Equipment

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Submitted By: Christian Erbe  
ERBE-USA  
2225 Northwest Parkway  
Suite 105  
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Contact Person: Scott Cundy

Date Prepared: August 12, 1999

Device Name: Common Name: Argon Plasma Coagulation (APC)  
Applicators for use with HF current  
ERBOTOM ICC Series Electrosurgery  
Systems.

Trade Name: ERBE APC Applicators

Proprietary Name: ERBE APC Applicators

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

Product Code: 79GEI

**Substantially Equivalent Devices:**

The ERBE APC Applicators are substantially equivalent to the following legally marketed devices: Beacon's Argon Beam Laparoscopic Electrode (K902996), Everest Medical's Bipolar Laparoscopic Cutting Electrosurgical Needle (K945975), and ERBE USA's APC Probes (K963189).

**Device Description:**

The APC Applicators are provided in various shaft lengths, shaft diameters, and bend angles to accommodate the variations in anatomical configuration of the target population and surgeon preference. The shaft lengths vary from 110 mm to 500 mm. The shaft diameters vary from 1.5 mm to 2.3 mm.

## 510(K) SUMMARY

### **Device Description:**

The APC Applicators work by using argon gas with a monopolar power source. The electrode in the argon channel of the applicator is connected to an electrosurgical generator. When high frequency voltage is high enough, and the proximity to tissue is close enough, electrically conductive argon plasma forms in the gas stream. This allows the current to flow between the applicator and the tissue. Current density upon arrival at the tissue surface causes coagulation. The application of the energy to the tissue is uniform and contact free. A silicon sleeve is available for APC Applicators with lateral openings at the distal end that are used in small lumen.

The APC Applicators' tips are either straight, curved, angled, or needle. The target population is both for laparoscopic and open electrosurgical procedures. The anatomical sites are for various general surgical procedures. The APC Applicators are made of PTFE shafts, ceramic tips, and Zytel and steel connector assemblies.

Both the flexible and rigid APC Applicators are provided non-sterile and are reusable using steam sterilization, whereas the other devices are provided sterile and are disposable. ERBE USA has conducted a sterilization validation per EN45001 to define and support the resterilization.

### **Intended Uses:**

The ERBE APC Applicators' intended use is for the delivery of argon gas plasma energy for coagulation of tissue.

The APC Applicators are used with the ERBOTOM ICC Series Electrosurgery Units and ERBE's APC 300 (K963189) Argon Plasma Coagulator.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 14 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992769  
Trade Name: ERBE APC Applicators  
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 enclosures) 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.

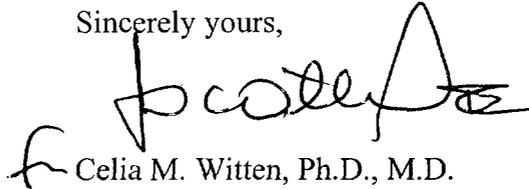
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

Enclosures

**INDICATIONS FOR USE**

K992769

- APC Coagulation

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

X

\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number \_\_\_\_\_

K992769