

K963189

ERBE

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Electrosurgical Equipment

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

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Date Summary Prepared: August 12, 1996

2. Name of the Device:

ERBE APC 300 Argon Plasma Coagulator and Accessories
(APC probe for flexible endoscopes)

3. Predicate Device Information:

Beamer 1/2/4/6/8, K#903724 manufactured by Beacon Laboratories, Inc.; and
Beacon B-101 Laparoscopic Switching Disposable Hand Piece, K#894762,
manufactured by Beacon Laboratories, Inc.

4. Device Description:

The APC 300 is a table-top device which allows for placement of an ERBE ICC Generator on its top cover. The front panel of the device provides access to and viewing of all controls and indicators. The device is designed to interface with APC flexible applicator probes. The device automatically sets a fixed

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argon gas flow to match the inner diameter of the three available flexible probes. The rate of gas flow for each flexible probe is as follows: 1.5 mm - 0.1 l/min to 0.5 l/min, 2.3 mm - 0.5 l/min to 2.4 l/min, 3.2 mm - 0.6 l/min to 5.0 l/min. The flow rates are also adjustable up to 9 l/min by accessing a special program via a "Program" button on the front panel, and utilizing an appropriately sized (diameter) probe to safely allow the flow rate desired.

There are two connections on the front panel, one for argon gas flow to a probe, the other for activation, either from a foot pedal or a finger-control handpiece. There is also a purge button on the front panel. A cable is provided on the rear panel of the device to be connected to the electrosurgical generator foot pedal control input.

There are inputs for two argon gas cylinders on the rear panel. Argon gas level, flow rate, operating and program information is indicated via liquid crystal display on the front panel. Gas cylinder changeover is automatic. The APC 300 Accessory Cart has four wheels (2 locking), a hospital grade power strip, storage shelf, and a compartment for two argon gas cylinders.

5. Intended Use:

The ERBE APC 300 Argon Plasma Coagulator is an argon gas delivery system that is designed for coagulation when used in combination with ERBE ICC Electrosurgery Generators and ERBE APC Probes.

6. Comparison to Predicate Devices:

Intended use for both devices is coagulation using pure argon. Gas flow rates are both automatic and adjustable, using both foot pedals and hand controls for activation. There are more standard indicators with the APC 300 and only a "gas flow" indicator for the program menu with the Beamer. The APC 300 applicator probe is flexible, whereas the Beamer utilizes a rigid probe.

The APC applicator probe is similar to Beacon's B-101 Laparoscopic Switching Disposable Hand Piece; the Beacon product is rigid and hand or foot switching and the APC probe is flexible and foot switching. Both devices provide a conduit to deliver argon gas from the machine to the patient.

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7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the ERBE APC 300 and APC Probe in the intended environment of use is supported by testing that was conducted in accordance with the FDA October 1993 Draft "510(k) Guideline for General Surgical Electrosurgical Devices", which outlines performance requirements.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards.

We certify that the ERBE APC 300 Argon Plasma Coagulator is designed to meet all applicable requirements of the ANSI/AAMI HF-18/1993 American National Standard for Electrosurgical Devices, as well as IEC 601-1-2.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the ERBE APC 300 Argon Plasma Coagulator and Accessories is as safe and effective as predicate devices presently on the market, based on electrical and mechanical results, as well as FDA guidance document criteria.