

K973820

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MAY 12 1998

510(k) Summary**#K973820**

- 1) **Submitter:** Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117
- Contact:** Dr. Ronald J. Ehmsen
(805) 961-3290
- Date Prepared:** May 7, 1998
- 2) **Name of Device:** CIRCON ACMI USA Elite System™ VaporTrode™ Vaporization Electrode and VaporTome™ Resection Electrode
- Proprietary/Trade Name:** CIRCON ACMI VaporTrode™ Vaporization Electrode and VaporTome™ Resection Electrode
- Common/Usual Name:** Electrode, Electrosurgical, Active, Urological
- Classification:** Class II (21 CFR §876.4300)
- Classification Name:** Endoscopic Electrosurgical Unit and Accessories (78FAS)
- 3) **Names of Predicate or Legally Marketed Devices:**
- CIRCON ACMI's USA Elite System™ VaporTrode™ Vaporization Electrodes are substantially equivalent¹ to the Grooved Roller Electrodes marketed by American Cystoscope Makers, Inc. (ACMI, a predecessor of CIRCON ACMI Division of Circon Corporation). These devices were confirmed to be preamendments devices in a letter dated August 31, 1995, from Mr. T. Wells of FDA's Office of Compliance. The VaporTome™ Resection Electrodes are substantially equivalent to the Resectoscope Cutting Loops marketed by American Cystoscope Makers, Inc., which are also preamendments devices.
- 4) **Description of Device:**
- CIRCON ACMI's USA Elite System™ VaporTrode™ Vaporization Electrodes and VaporTome™ Resection Electrodes are electrosurgical electrodes used in CIRCON ACMI's resectoscopes utilizing a direct connection between the electrode and the active cord of the electrosurgical generator.

¹The term, "substantially equivalent," is intended to reflect a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing on matters relating to patents.

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5) Intended Use of Device:

CIRCON ACMI's USA Elite System™ VaporTome™ Vaporization Electrodes and VaporTome™ Resection Electrodes are indicated for use in urology for cutting, coagulation, and vaporization of soft tissue, including prostatic and bladder tissue and the treatment of benign prostatic hyperplasia (BPH) and bladder cancer.

6) Comparison of Technological Characteristics:

CIRCON ACMI's USA Elite System™ VaporTome™ Vaporization Electrodes and VaporTome™ Resection Electrodes are substantially equivalent² to the American Cystoscope Makers, Inc. Grooved Roller Electrodes and Resectoscope Cutting Loops, respectively. Those preamendments devices employed similar design considerations and operating principles. Any differences between these devices do not raise new questions regarding safety or effectiveness.

²The term, "substantially equivalent," is intended to reflect a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing on matters relating to patents.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ronald J. Ehmsen, Sc.D.
Vice President, Regulatory Affairs
CIRCON Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117-3019Re: K973820
Circon ACMI USA Elite System™ Vaporization
Electrode and VaporTome™ Resection Electrode
Dated: March 16, 1998
Received: March 20, 1998
Regulatory Class: II
21 CFR 876.4300/Procode: 78 FAS

Dear Dr. Ehmsen:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K973820

Device Name: Circon ACMI USA Elite System™ Vaporization Electrode
and VaporTome™ Resection Electrode

Indications for Use:

Circon ACMI's USA Elite System™ VaporTrode™ Vaporization Electrodes and VaporTome™ Resection Electrodes are indicated for use in urology for cutting, coagulation, and vaporization of soft tissue, including prostatic and bladder tissue and the treatment of benign prostatic hyperplasia (BPH) and bladder cancer.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Nutting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use (Per 21 CFR 801.109) 510(k) Number K973820 OR Over-The-Counter Use (Optional Format 1-2-96)