NOV 17 1998

510(k) Summary: #K980492

Applicant: Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117
(805) 685-5100

Contact: Ronald J. Ehmsen, Sc.D., Vice President, Regulatory Affairs

Device Identification:

Proprietary Name: CIRCON ACMI AEH-3™
Electrohydraulic Lithotripter and Probes
Common/Usual Name: Electrohydraulic Lithotripter (Intracorporeal) and Accessories
Classification Name: Electrohydraulic Lithotriptor

Device Classification: Class III (Currently undergoing review of reclassification petition to reclassify to Class II).

Substantial Equivalence:

CIRCON ACMI's AEH-3 Electrohydraulic Lithotripter and Probes are substantially equivalent[1] in design, materials and intended use to other devices that are legally marketed for the same intended uses. Such devices are currently manufactured by Northgate Technologies, Inc., Karl Storz Endoscopy-America, Inc. and Richard Wolf Medical Instruments Corporation.

Intended Use:

CIRCON ACMI's AEH-3 Electrohydraulic Lithotripter and Probes are intended to be used to fragment stones (calculi) in the urinary and biliary tracts, including the kidney, ureter, bladder, urethra, and common bile duct.

Device Description:

The CIRCON ACMI AEH-3 Electrohydraulic Lithotripter is a bipolar electronic device. When used with its flexible probes, the system is capable of fragmenting calculi so that fragments can be removed without requiring major surgery. In the presence of recommended irrigant solutions, sparks produced by activating the AEH-3 generator produce a series of high amplitude hydraulic shock waves that initiate fragmentation. These shock waves have no adverse effect on tissue because of tissue flexibility, as long as the probe does not come in contact with the tissue surface.

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[1] The 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1998

Ronald J. Ehmsen, Sc. D.
Vice President, Regulatory Affairs
Circon Corporation
6500 Hollister Avenue
Santa Barbara, California 93117-3019

Re: K980492
AEH-3 Electrohydraulic Lithotripter and Probes
Dated: September 10, 1998
Received: September 11, 1998
Regulatory Class: III
21 CFR 876.4480/Procode: 78 FFK

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: K980492

Device Name: AEH-3 Electrohydraulic Lithotripter and Probes

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980492