AUG - 3 1999

510(k) Summary

#K992126

1) **Submitter:** Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Contact: Dr. Ronald J. Ehmsen
(805) 961-3290 (tel.) or (805) 968-7385 (fax)

Date Prepared: June 18, 1999

2) **Name of Device:** Battery-Powered Irrigation Pump for Suction-Irrigation System

Proprietary/Trade Name:

Circon Surgiflex® WAVE® Tsunami™ Suction-Irrigation System

Common/Usual Names: Irrigation Pump; Suction-Irrigation Probe

Classification: Class II (21 CFR §876.1500 and §884.1720).

Classification Names: Endoscope and accessories; Gynecologic laparoscope and accessories.

3) **Names of Predicate or Legally Marketed Devices:**

Circon's Surgiflex® WAVE® Tsunami™ Suction-Irrigation System is substantially equivalent to Cabot Medical Corporation's Surgiflex® Suction-Irrigation Probes that were cleared by FDA for marketing on 06/08/94 under 510(k) #K932626; Davol's Hydro-Surg® Laparoscopic Irrigator that was cleared by FDA for marketing on 05/15/96 under 510(k) #K961492; and Stryker's Laparoscopic Suction Irrigator that was cleared by FDA for marketing on 02/18/94 under 510(k) #K934094. (A modification of Stryker's Laparoscopic Suction Irrigator was subsequently cleared for marketing on 11/29/95 under 510(k) #K954726.) These predicate devices are legally marketed for the same intended use (i.e., suction-irrigation during laparoscopic and open surgical procedures).

4) **Description of Device:**

The Circon Surgiflex® WAVE® Tsunami™ Suction-Irrigation System is comprised of a Tsunami™ Battery-Powered Pump that may be attached to a source of irrigation fluid (generally a bag containing sterile normal saline), a length of irrigation tubing connected to a Surgiflex® WAVE® suction-irrigation handpiece, and a length of suction tubing connected between the handpiece and a vacuum source (usually a suction canister that is connected to a wall suction outlet). Irrigation solution is introduced to the surgical site and fluids, debris and smoke are evacuated from the site via a disposable suction-irrigation probe. All components of the system are supplied sterile, disposable in a sealed plastic tray for single patient use.

5) Intended Use of Device:

Circon Corporation's Tsunami™ Battery-Powered Irrigation Pump is intended to be used in conjunction with Circon's Surgiflex® WAVE® Tsunami™ Suction-Irrigation System to provide controlled, powered delivery of sterile irrigation fluids to surgical sites and to evacuate blood, tissue debris and smoke from the operative field to aid in visualization during laparoscopic and open surgical procedures. The system may also be used for resection of filmy adhesions and for peritoneal lavage.

6) Comparison of Technological Characteristics:

Circon's Surgiflex® WAVE® Tsunami™ Suction-Irrigation System is substantially equivalent[1] to Cabot's Surgiflex® Suction-Irrigation Probes, Davol's Hydro-Surg® Laparoscopic Irrigator and Stryker's Laparoscopic Suction Irrigator. All of these devices employ substantially equivalent design considerations and operating principles, and their materials of construction are safe for the intended uses. All of these devices are supplied sterile for single-use only, and none actively delivers any form of electrical energy to the patient. Any differences between the various devices do not raise new questions regarding safety or effectiveness.

[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

AUG - 3 1999

Dr. Ronald J. Ehmsen
Vice President, Regulatory Affairs
Circon Corporation
6500 Hollister Avenue
Santa Barbara, California 93117

Re: K992126
Trade Name: Circon Surgiflex® WAVE Tsunami™ Suction-Irrigation System
Regulatory Class: II
Product Code: GCX
Dated: June 18, 1999
Received: June 23, 1999

Dear Dr. Ehmsen:

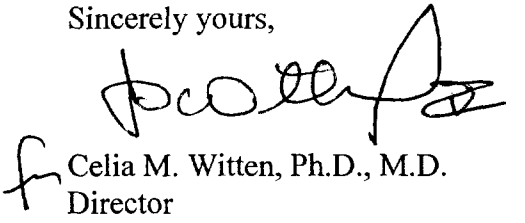
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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,



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

510(k) Number: K992126

Device Name: Battery-Powered Irrigation Pump for Circon's Suction-Irrigation System

Indications for Use:

Circon Corporation's Tsunami™ Battery-Powered Irrigation Pump is intended to be used in conjunction with Circon's Surgiflex® WAVE® Tsunami™ Suction-Irrigation System to provide controlled, powered delivery of sterile irrigation fluids to surgical sites and to evacuate blood, tissue debris and smoke from the operative field to aid in visualization during laparoscopic and open surgical procedures. The system may also be used for resection of filmy adhesions and for peritoneal lavage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992126

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)