OCT 26 1999

510(k) Summary

#K992544

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

Contact: Dr. Ronald J. Ehmsen
(805) 961-3290

Date Prepared: July 23, 1999

2) **Name of Device:** Rigid Operative Culdoscopy Accessories

Proprietary/Trade Name: Transvaginal Hydro®Laparoscopy (THL™) System

Common/Usual Name: Culdoscope and Accessories

Classification: Class II (21 CFR §884.1640)

Classification Name: Culdoscope and Accessories

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

Circon's Rigid Operative Culdoscopy Accessories are substantially equivalent to ACMI's Decker Operating Culdoscope and accessories and to Circon's Rigid Culdoscope and Accessories. The Decker devices were legally marketed for the same intended use (i.e., culdoscopy) prior to May 28, 1976, and the Circon devices were cleared under 510(k) #K980972 on June 12, 1998.

4) **Description of Device:**

Circon's Rigid Operative Culdoscopy Accessories consist of several tubular stainless steel components. During culdoscopy, light from a high intensity light source is transmitted to a rigid culdoscope by a fiber optic light guide that is detachably connected to a light post on the body of the scope. The light is carried by the illumination fibers to the target. A distal lens focuses an image of the target onto the rod lens train. The image is transmitted to the proximal end of the scope, where it is magnified and focused by an eyepiece ocular. The image may be viewed directly through the eyepiece, or the scope may be connected to a video system via a standard endoscopic video coupler. In order to perform operative procedures, the operative cannula of the subject system replaces the smaller diagnostic cannula of the predicate system, and an operative sheath replaces the smaller diagnostic sheath of the predicate system. A channel is formed between the culdoscope and the operative sheath, thereby allowing passage of small instruments for a variety of operative procedures.

5) **Intended Use of Device:**

Circon's Rigid Operative Culdoscopy Accessories are intended to be used with Circon's Rigid Culdoscope and Accessories for viewing pelvic organs endoscopically via a posterior vaginal fornix entry for the purpose of performing diagnostic and operative procedures on the female genital organs. Indications for use are:

- Unexplained pelvic pain (acute, chronic)
- Menstrual abnormalities
- Infertility and sterility
- Indefinite pelvic mass
- Ectopic pregnancy
- Pelvic endometriosis
- Polycystic ovaries
- Pelvic inflammatory disease (PID)
- Pain mapping
- Congenital anomalies of the pelvic organs
- Lysis of adhesions
- Cytology sampling
- Biopsy

6) **Comparison of Technological Characteristics:**

Circon's Rigid Operative Culdoscopy Accessories are substantially equivalent[1] to the ACMI Decker Operating Culdoscope and to the Circon Rigid Culdoscopes and Accessories. Circon's operative accessories employ the same design considerations and operating principles as the legally marketed predicate devices, and each can be cleaned, sterilized and reused. Any differences between these 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

OCT 26 1999

Ronald J. Ehmsen, Sc.D.
Vice President
Regulatory Affairs
CIRCON CORPORATION
6500 Hollister Avenue
Santa Barbara, CA 93117-3019

Re: K992544
Rigid Operative Culdoscopy Accessories
Dated: July 28, 1999
Received: July 30, 1999
Regulatory Class: II
21 CFR 884.1630/Procode: 85 HEX

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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.
Acting 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: K992544

Device Name: Circon Rigid Operative Culdoscopy Accessories

Indications for Use:

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

Concurrence of CDRH, Office od Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992544