K980972

JUN 12 1998

510(k) Summary

#K98 0972

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

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

Date Prepared: March 12, 1998

2) **Name of Device:** Rigid Culdoscope and Accessories

Proprietary/Trade Name: (Not yet determined)

Common/Usual Name: Culdoscope

Classification: Class II (21 CFR §884.1640)

Classification Name: Culdoscope and Accessories

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

CIRCON's Rigid Culdoscopes and Accessories are substantially equivalent to ACMI's Decker Culdoscope and Decker Operating Culdoscope, to Karl Storz Endoscopy America, Inc.'s Culdoscopes and to Richard Wolf Medical Instrument Corp.'s Fiber Light Culdoscopes. All of these devices were legally marketed for the same intended use (i.e., culdoscopy) prior to May 28, 1976.

4) **Description of Device:**

CIRCON's Rigid Culdoscopes and Accessories are rod lens-type endoscopes which consist of imaging optics and fiber optic illumination fibers contained within a stainless steel sleeve. Light from a high intensity light source is transmitted to the scope 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.

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5) Intended Use of Device:

CIRCON's Rigid Culdoscopes and Acessories are intended to be used for direct viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures. The system is introduced into the pelvic cavity through the posterior vaginal fornix.

6) Comparison of Technological Characteristics:

CIRCON Rigid Culdoscopes and Accessories are substantially equivalent[1] to the Decker Culdoscopes and Decker Operating Culdoscopes that were first marketed by ACMI, and to the Storz and Wolf culdoscopes. CIRCON's scopes employ the same design considerations and operating principles as the legally marketed predicate devices, and each can be sterilized and reused. Any differences between these culdoscopes do not raise new questions regarding safety or effectiveness.

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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

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

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Re: K980972
Rigid Culdoscopes and Accessories, G27 Series (Diagnostic Use)
Dated: March 12, 1998
Received: March 16, 1998
Regulatory Class: II
21 CFR 884.1640/Procode: 85 HEW

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: K980972

Device Name: Rigid Culdoscopes and Accessories

Indications for Use:

Circon's Rigid Culdoscopes and Accessories are intended for viewing pelvic organs endoscopically via a posterior vaginal fornix entry. Culdoscopy is indicated for:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980972