K012758

APR - 9 2002

510(k) SUMMARY

ACMI Circon' SEMI-RIGID URETEROSCOPES

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

ACMI Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Phone: 805-961-3290
Fax: 805-968-7385

Contact Person: Mr. Wayne B. Sterner
Corporate Director Regulatory Affairs

Date Prepared: February 8, 2002

Name of Device and Name/Address of Sponsor:

ACMI Circon's Semi-Rigid Ureteroscopes

ACMI Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Common or Usual Name:

Ureteroscopes

Classification Name and Classification Number:

Endoscope and accessories, 21 CFR Section 876.1500

Predicate Device(s):

The predicate device is an ACMI Circon preamendment ureteroscope (circa, 1971).

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Intended Use:

ACMI Circon's Semi-Rigid Ureteroscopes are intended for use by qualified physicians to provide access to the urinary tract to perform various diagnostic and therapeutic procedures.

Technological Characteristics and Substantial Equivalence:

ACMI Circon's Semi-Rigid Ureteroscopes are substantially equivalent to other currently marketed ureteroscopes, referenced above. The Semi-Rigid Ureteroscopes and their predicate device(s) are all telescopes that incorporate fiber optics, optical lenses and working channels within a semi-rigid shaft. The working channels of the Semi-Rigid Ureteroscopes and predicate device(s) allow the insertion of accessory instrumentation during urinary tract procedures. Both the Semi-Rigid Ureteroscopes and the predicate device(s) may be connected to an external light source to permit better illumination of the bladder surfaces.

The ACMI Circon's Semi-Rigid Ureteroscopes raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Mr. Wayne B. Sterner
Director, Regulatory Affairs
ACMI Circon Corporation
6500 Hollister Avenue
SANTA BARBARA CA 93117-3019

Re: K012758
Trade/Device Name: Semi-Rigid Ureteroscopes and Accessories
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FGB
Dated: February 8, 2002
Received: February 11, 2002

Dear Mr. Sterner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012758

CIRCON CORPORATION
Semi-Rigid Ureteroscopes and Accessories
FDA Premarket Notification 510(k)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Semi-Rigid Ureteroscopes and Accessories

The intended use for these Semi-Rigid ureteroscopes is for examination/operation of the urinary tract and, using additional accessories, to perform various diagnostic and therapeutic procedures.

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

Concurrence of CRDH, Office of Device Evaluation (ODE)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012758

Prescription Use ✓
(Per 21 CFR 801.109)