K013165

JAN 1 8 2002

510(k) SUMMARY

CIRCON's USA Series™ Laparoscopes

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

CIRCON Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Phone: (805) 961-3290
Facsimile: (805) 968-7385

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

Date Prepared: 9-20-01

Name of Device and Name/Address of Sponsor

CIRCON's USA Series™ Laparoscopes with various Tradenames

CIRCON Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Common or Usual Name

Laparoscopes

Classification Name

Laparoscope, General and Plastic Surgery

Predicate Devices

Richard Wolf's Operating Laparoscopes (K991718);
Smith and Nephew Dyonics 2.7 mm Microlaparoscope (K982149);
Karl Storz's MVM 3.3 mm Microendoscope (K972504);
Surgical Image Laboratories, Inc.'s Model LL100, 103, and 104 Laparoscopes (K955845); and
Surgical Image Laboratories, Inc.'s 3.5 mm Laparoscope (K001594);

K013165

Intended Use

CIRCON's USA Series™ Laparoscopes have the same general intended use as the previously cleared predicate devices. The USA Series™ Laparoscopes are intended for use by qualified physicians to provide access, illumination and visualization of body cavities, hollow organs, and canals during endoscopic and laparoscopic surgical procedures. These include, but are not limited to, laparoscopic procedures used in general surgical procedures, cholecystectomy, colon resection, and therapeutic thoracoscopy.

Technological Characteristics and Substantial Equivalence

CIRCON's USA Series™ Laparoscopes are substantially equivalent to the other currently marketed laparoscopes which are referenced above. CIRCON's USA Series™ Laparoscopes and their predicate devices are all telescopes that incorporate fiber optics and optical lenses within a rigid shaft and are connected to an external light source. Several models of CIRCON's USA Series™ Laparoscopes and predicate devices also incorporate a working channel within the diameter of the rigid shaft that allows throughput of accessory instrumentation for use during laparoscopic surgical procedures. Thus, CIRCON's USA Series™ Laparoscopes raise no new issues of safety or effectiveness.

Biocompatibility

All CIRCON USA Series™ Laparoscopes are made of medical grade biocompatible materials and are of the same type of material as used in other 510(k) cleared predicate laparoscopes that have the same body contact, contact duration, and intended use and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

ACMI Circon Corporation
Mr. Wayne B. Sterner
Corporate Director Regulatory Affairs
6500 Hollister Avenue
Santa Barbara, California 93117-3019

Re: K013165
Trade Name: USA Series Laparoscopes
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 4, 2002
Received: January 7, 2002

Dear Mr. Sterner:

We have reviewed your Section 510(k) premarket 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) 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 such 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 Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013165

Device Name: CIRCON's USA Series™ Laparoscopes

Indications for Use:

CIRCON's USA Series™ Laparoscopes are intended for use by qualified physicians to provide access, illumination and visualization of body cavities, hollow organs, and canals during endoscopic and laparoscopic surgical procedures. These include, but are not limited to, laparoscopic procedures used in general surgical procedures, cholecystectomy, colon resection or therapeutic thoracoscopy.

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

Concurrence of CDRH, Office of 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 General, Restorative
and Neurological Devices

510(k) Number K013165

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