

JAN 18 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);

## **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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JAN 18 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.

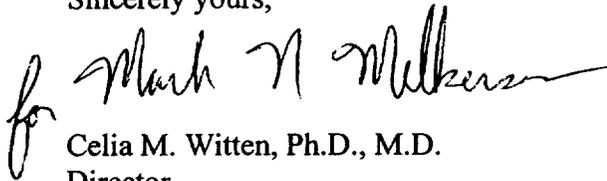
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Wayne Sterner

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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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.

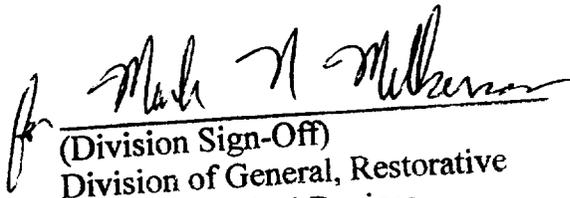
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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