COMEG
Endoscopy

K971881 AUG 12 1997

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SUMMARY OF SAFETY AND EFFECTIVENESS FOR RESECTOSCOPE AND LASER-RESECTOSCOPE WORKING ELEMENTS, ALBARRAN DEFLECTORS, URETHROTOMES, AND ELECTRODES

§807.92 (a)(1)

Contact Person: Peter Duffy
Vice President

Date of Summary Preparation: May 16, 1997

§807.92 (a)(2)

Trade Name: COMEG Endoscopy Resectoscope and Laser-Resectoscope Working Elements, Albarran Deflectors, Urethrotomes, and Electrodes

Common Name: Endoscopes and accessories

Classification Name: Endoscope and accessories (21 CFR §876.1500)
Urethrotome (21 CFR §876.4770)
Endoscope ESU unit and accessories (21 CFR §876.4300)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Karl Storz and Circon ACMI

§807.92 (a)(4)

Description of Device: The COMEG devices that we intend to market include the following endoscopic electrosurgical instruments and accessories: resectoscope and laser-resectoscope working elements; Albarran deflectors; urethrotomes (urethrotome bridges, obturators, and knives); high frequency cable; and, electrodes. A "Quick-Connection" feature is used to attach the device to the sheath or working element.

Endoscopic electrosurgical instruments and accessories are described in endoscope and accessories 21 CFR §876.1500, urethrotomes are described in 21 CFR §876.4770, and endoscope ESU unit and accessories are described in 21 CFR §876.4300.

The Resectoscope and Laser Resectoscope Working Elements are intended to be used in urological procedures to endoscopically remove, cut, coagulate, and/or transect tissue in the bladder, prostate, and/or urethra. The surgeon performs the examination through the urethra. The working elements are devices that house and control the various electrodes and lasers used to remove, cut, coagulate, and transect tissue. The doctor controls the

back and forth movement of the electrode using finger controls. The working elements also house a cystoscope for visualization. The high frequency cable transmits electrical current.

These devices are composed of stainless steel chrome plated, plastic, and brass chrome plated. The high frequency cable is composed of silicone.

Albarran deflectors are intended for use in urological procedures to control the flexible instrumentation that is passed through the COMEG cystoscope sheaths.

These devices are composed of stainless steel chrome plated and brass chrome plated.

The intended use for the urethrotomes is in urological procedures to endoscopically cut and/or transect tissue (strictures) in the urethra. The surgeon performs this function through the urethra and will visually (cystoscope) find the location of the stricture in the urethra. Once the stricture is located a urethrotome will be extracted, cutting the affected area.

These devices are composed of stainless steel chrome plated, plastic, and brass chrome plated. The complete working unit is comprised of each of the models below plus a cystoscope.

The electrodes are intended to be used endoscopically in conjunction with COMEG resectoscopes, urethrotomes, or cystoscope sheaths. The purpose of the electrodes is for cutting, tissue removal, tissue vaporization, coagulation, and/or transection of tissue. Electrodes are connected to either a resectoscope working element or a high frequency cable. The electrodes are reusable.

These electrodes are composed of stainless steel, teflon, silicone, ultem (black plastic), tungsten, and silver.

§807.92 (a)(5)

Intended Use: See Device Description above.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The subject devices are similar to devices marketed by Karl Storz and Circon ACMI. The predicate device for the Quick-Connection feature is Circon ACMI. The intended uses for the subject devices are the same for the subject devices and the competitors' products. The materials used to fabricate both the COMEG and the Karl Storz devices and the operational principles and mode of action are similar as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1997

Mr. Peter Duffy
Vice President
COMEG Endoscopy
13790 E. Rice Place
Aurora, Colorado 80015

Re: K971881
COMEG Resectoscope and Laser-Resectoscope Working Elements, Urethrotomes (bridges, obturator, and knives), and Electrodes
Dated: May 16, 1997
Received: May 20, 1997
Regulatory Class: II
21 CFR §876.1500, 876.4770, and 876.4300
Product Code: FJL, FDC, EZO, and FAS

Dear Mr. Duffy

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 requirement, 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/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

COMEG
Endoscopy

Indications for Use

510(k) Number (if known) K971881
Device Name: Endoscopic electrosurgical instruments and accessories

Indications for Use:

Resectoscope and Laser Resectoscope Working Elements are intended to be used in urological procedures to endoscopically remove, cut, coagulate, and/or transect tissue in the bladder, prostate, and/or urethra. The surgeon performs the examination through the urethra. The working elements are devices that house and control the various electrodes and lasers used to remove, cut, coagulate, and transect tissue. The doctor controls the back and forth movement of the electrode using finger controls. The working elements also house a cystoscope for visualization. The high frequency cable transmits electrical current.

Albarran deflectors are intended for use in urological procedures to control the flexible instrumentation that is passed through the COMEG cystoscope sheaths.

Urethrotomes are intended to be used in urological procedures to endoscopically cut and or transect tissue(strictures) in the urethra. The surgeon performs this function through the urethra and will visually (cystoscope) find the location of the stricture in the urethra. Once the stricture is located a urethrotome knife will be extended an the entire urethrotome will be extracted cutting the affected area.

Electrodes are intended to be used endoscopically im conjunction with COMEG resectoscopes, urethrotomes, or cystoscope sheaths. The purpose of the electrodes is for cutting, tissue removal, tissue vaporization, coagulation, and/or transection of tissue. Electrodes are connected to either a resectoscope working element or a high frequency cable. The electrodes are reusable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use K (Per 21 CFR 801.109) OR Over-the-Counter Use_____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971881