COMEG
Endoscopy

K971202
P192

SUMMARY OF SAFETY AND EFFECTIVENESS FOR COMEG OPTICAL BIOPSY FORCEPS, UROLOGICAL VISUAL OBTURATORS, OPTICAL STONE CRUSHING FORCEPS

§807.92 (a)(1)

Contact Person: Peter Duffy
Vice President

Date of Summary Preparation: March 28, 1997

§807.92 (a)(2)

Trade Name: COMEG Optical Biopsy Forceps
COMEG Urological Visual Obturators
COMEG Optical Stone Crushing Forceps

Common Name: Endoscopes and accessories

Classification Name: Endoscope and accessories (21 CFR §876.1500)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Karl Storz Short Jaw Biopsy Forceps, Visual Obturators for Cystoscopes - Urethroscopes, Kidney Stone Crusher

§807.92 (a)(4)

Description of Device: Endoscopes and accessories are described in 21 CFR §876.1500. The COMEG Endoscopy devices that we intend to market include Optical Biopsy Forceps, Urological Visual Obturators, and Optical Stone Crushing Forceps. The stainless steel of which the devices are fabricated is ASTM type 304 which meets the ASTM specification F899-84 Standards for Stainless Steel Billet, Bar and Wire for Surgical Instruments and is biocompatible with human tissue. The devices can be reused and instructions for cleaning and sterilization will be provided.

§807.92 (a)(5)

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Intended Use:

Optical Biopsy Forceps - The intended use is in urological procedures to endoscopically remove tissue for evaluation.

Urological Visual Obturators - The intended use is in urological procedures to endoscopically examine and allow access to the urethra and bladder. The obturator is inserted into the sheath and its blunt end protrudes from the distal end. It protects the tissue when the sheath is entered into the area under examination. The visual obturator has a cystoscope directly inserted in the center of the obturators to allow for visualization while entering the subject.

Optical Stone Crushing Forceps - The intended use for the optical stone crushing forceps is in urological procedures to endoscopically remove, manipulate, crush, or grasp calculi (i.e. stones) and other foreign objects.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The subject devices are similar to devices marketed by Karl Storz. The "Quick-Connection" feature is also used in COMEG Resectoscope accessories (K970764). The intended uses are the same for the subject devices and the competitor's product. 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

MAY 27 1997

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

Re: K971202
COMEG Optional Stone Crushing Forceps, Visual Obturators, and Optical Biopsy Forceps
Dated: March 28, 1997
Received: April 1, 1997
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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) K971202
Device Name: COMEG Optical Biopsy Forceps, Urological Visual Obturators, Optical Stone Crushing Forceps

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 801.109)

Robert P. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971202