K972505

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SECTION II
SAFETY AND EFFECTIVENESS SUMMARY

SEP 18 1997

SAFETY AND EFFECTIVENESS
MONOPOLAR BIOPSY FORCEPS SUMMARY

The Summary of Safety and Effectiveness on the endoscopic procedures for biopsy of upper or lower gastrointestinal tract and the Monopolar Biopsy Forceps used reflects data available and presented at the time the submission was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

The Reusable hot biopsy forceps are intended for use in flexible endoscopy procedures to biopsy, grasp, dissect and transect tissue.

Lesions/polyps of the lower or upper gastrointestinal tract may be biopsied for the purpose of diagnosing malignancies and other disorders.

The lesion/polyp is grasped between the jaws of the biopsy forceps; the forceps are then lifted from the intestinal wall and the tissue is ablated with electric current.

Contraindications for Biopsy Procedure

The use of Monopolar Biopsy Forceps is contraindicated and is not appropriate in cases where patients have or are present with:

- Coagulopathy
- Potential for bleeding
- Current use of anticoagulants
- Recent ingestion of non-steroidal anti-inflammatory or ASA-containing drug (unless bleeding is verified as normal)
- Other contraindications as determined by physician

Manufacturing Overview

U.S.E. manufactures and tests the product to performance specifications based on predicate and/or substantially equivalent devices.

U.S.E. manufacturing processes and procedures are based on good manufacturing practices. Quality assurance methods and procedures based on MIL-STD-9858 are utilized to assure conformance to design specifications.

Materials used in the manufacturing process are certified to standards appropriate for their use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Gretchen Younker Cohen
United States Endoscopy Group, Inc.
9330 Progress Parkway
Mentor, Ohio 44060

SEP 18 1997

Re: K972505
Reusable Hot Biopsy Forceps
Dated: June 30, 1997
Received: July 3, 1997
Regulatory class: II
21 CFR §876.4300/Product code: 78 KGE

Dear Ms. Cohen:

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

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510(k) Number if Known K972505

Device Name: Reusable Biopsy Forceps, Hot

Indications for Use:

The Reusable Hot Biopsy Forceps are intended for use in flexible endoscopy procedures to biopsy, grasp, dissect and transect tissue.

(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 R Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972505