

JUN 20 1997

SECTION II
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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COAXIAL NEEDLE

The Summary of Safety and Effectiveness on the Coaxial Needle 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 Coaxial Needle is used for endoscopic injection to control bleeding or lift sessile polyps using various media. An irrigation tube or syringe may be attached to the aspiration port of the needle in order to flush the injection site for better visualization.

Contraindications for the Coaxial Needle

The use of a Coaxial Needle is contraindicated in the following:

1. Uncooperative patient
2. Severe Coagulopathy

The physician will determine the patient's appropriateness for the procedure.

Manufacturing Overview

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

U.S.E.'s manufacturing processes and procedures are based on the Quality Systems Regulations. 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.

Sterilization

The Coaxial Needle will be sterilized using EtO.

Bibliography

Drossman, D.A. (Editor). (1987). Manual of Gastroenterologic Procedures (2nd Edition). New York: Raven Press

Ravenscroft, M.M. and Swand, C.H.J. Gastrointestinal Endoscopy and Related Procedures: A Handbook for Nurses and Assistants. Baltimore: Williams & Wilkens, 1984.

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Society of Gastroenterology Nurses & Associates. SGNA Manual of Gastroenterology Procedures. Rochester: SGNA, 1989.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K971842
Coaxial Needle
Dated: March 13, 1997
Received: May 19, 1997
Regulatory class: II
21 CFR §876.1075/Product code: 78 FCG

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 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

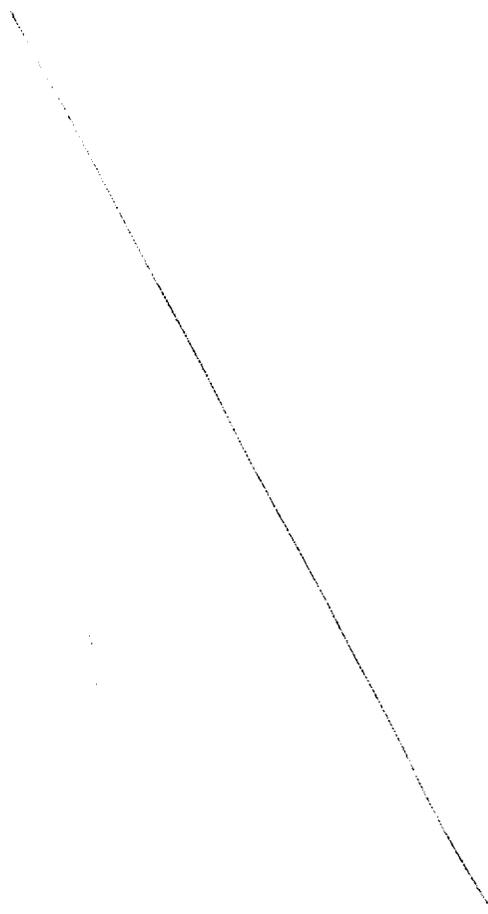
Enclosure

510(k) Number if Known K 9718⁴²

Device Name: Coaxial Needle

Indications for Use:

The Coaxial Needle is used for endoscopic injection to control bleeding or lift sessile polyps using various media. An irrigation tube or syringe may be attached to the aspiration port of the needle in order to flush the injection site for better visualization.



(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 S. Sathiyaj 14
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K9718⁴²