MAY 23 1997

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Endo SmartCap™ Company

16800 Imperial Valley Drive, Suite 312
Houston, TX 77060
(281) 999-4442 (713)445-0019 FAX

Contact Person: Mr. Don Byrne, President
Date this summary was prepared: March 13, 1997

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is _____

1. Trade Name: The Endo Smart Cap™
   Common Name: Sterile Water Bottle Adapter
   Classification Name: Endoscopes and Accessories

2. Predicate Device: The Endo SmartCap™ is substantially equivalent to a device currently in commercial distribution and marketed in the United States by

   Olympus America Inc.
   Two Corporate Center Drive
   Melville, NY 11747-3157

   as the Olympus Model Number MD-431 Water Container. The Olympus MD-431 Water Container is sold as part of the Olympus Series Number 10, 100 or 130 Endoscope and accessories.

— ATTACHMENT L

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Endo SmartCap™
510(k) Summary of Safety and Effectiveness
March 13, 1997

3. Description: The Endo SmartCap™ consists of two tubes, arranged coaxially, with a fitting on one end and a bottle cap adapter on the other. On one end, the tubes engage a coaxial fitting designed to replicate the fitting of the predicate device and how it engages with the receptacle on the Endoscope. The fitting is designed to receive air from the Endoscope and direct the flow through the annulus between the inner and outer tubes. The opposite end of the outer tube is connected to a bottle cap adapter by means of a compression fitting to form an airtight seal. The inner tube passes through the compression fitting and extends beyond the cap adapter. When assembled with a bottle of sterile water, the device allows air from the Endoscope to pressurize the bottle and motivate water out of the bottle through the inner tube. The inner tube terminates at the coaxial fitting where water is directed through a separate channel of the receptacle to feed the Endoscope.

   The Endo SmartCap™ is sold as a sterile, single patient use device. It will be individually packaged in a Chevron-style sterile barrier pouch with the product label affixed to the clear side of the package, or the label pre-printed on the Tyvek® side of the pouch.

4. Intended Use: The Endo SmartCap™ is intended to supply sterile water to series 10, 100 and 130 Olympus endoscopes when connected to a commercially available sterile water bottle.

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5. Summary of Technological Characteristics:

5.1 Design: The predicate device consists of a system comprised of a refillable plastic water bottle made of autoclavable materials, and a bottle cap/tube set/connector assembly which, together as a set, are designed to be cleaned, disinfected, autoclaved, and reused. According to the manufacturer's Instructions for Use (see Attachment "F"), the predicate device's manufacturer requires the user to "... Maintain the water container daily. The water container should be emptied, cleaned, and disinfected or sterilized at least once per day. Water bottles which are not maintained property (properly) may present an infection control risk."

The Endo SmartCap™ consists of a bottle cap/tube set/connector made of materials which are appropriate for the application, but are selected for single use, only. The applicant's device fits the three largest U.S. sterile water suppliers' bottles (sold by Abbott Laboratories, McGaw, and Baxter Healthcare). By attaching the Endo SmartCap™ to the sterile water bottle, the applicant's device becomes a replacement for the predicate device. By replacing a reusable device with a single use, disposable device, the risks associated with cross-contamination -- which are inherent with reusable devices -- are eliminated.

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5.2 Sterilization: The predicate device is intended for autoclave sterilization by the user, while the Endo SmartCap™ is sterilized by Ethylene Oxide and is sold sterile as a single patient use device.

6. Performance

6.1 Bench Testing: Bench testing of the applicant's device and the predicate device was performed using the same Endoscope system and in a manner which emulates the product in use. The two output variables which are the subject of this test were water flow rate and static pressure rating.

6.2 Flow Test Results: Flow rate tests demonstrate that the applicant's device delivers the same flow rate under a variety of pressure settings as the predicate device, within reasonable measurement error (+/-4%).

6.3 Pressure Test Results: According to the Olympus Endoscope manual, the air pump is rated to produce a maximum of 0.32 kg/cm^2 (4.4 PSI). The applicant's device was tested to 10 PSI using sterile water bottles from the three largest sterile water manufacturers (Abbott, Baxter and McGaw) without leaking or any other failure.

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6.3 Justification of Determination of Substantial Equivalence

The Endo SmartCap™ differs from the predicate device in design, materials and sterilization methods, however the performance of the two devices in use are quite similar. Although the materials of construction are different from the predicate, the differences are justifiable when the reusable versus disposable application is taken into consideration, and no new questions are raised regarding safety and effectiveness.

7. Conclusion

The Endo SmartCap™ was tested and proven to withstand at least twice the static pressure the Endoscope air pump is capable of delivering. In flow tests, the Endo SmartCap™ delivered a flow rate which was indistinguishable from the predicate device without precision measurement techniques. It was therefore concluded that the Endo SmartCap™ demonstrated equivalency in its performance as compared to the predicate device.

Don Byrne 3-18-97

Don Byrne, President Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1997

Mr. Don Byrne
President
Endo SmartCap™ Company
16800 Imperial Valley Drive, Suite 312
Houston, Texas 77060

Re: K971125
The Endo SmartCap™ Sterile Water Bottle Adaptor
Dated: March 18, 1997
Received: March 27, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Mr. Byrne:

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 97 1125

Device Name: Endo SmartCap™ Sterile Water Bottle Adaptor

Indications For Use:

The Endo SmartCap™ is intended to supply sterile water to series 10, 100 and 130 Olympus endoscopes when connected to a commercially available sterile water bottle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971125

Prescription Use ____ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format**