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510(k) SUMMARY
FOR THE US ENDOSCOPY
IRRIGATION PUMP AND VALVE SYSTEM

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

Applicant: United States Endoscopy Group, Inc.
5976 Heisley Road
Mentor, Ohio 44060

Contact Person: Craig L. Moore
General Counsel
5976 Heisley Road
Mentor, Ohio 44060
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Device Common Name: Irrigation Pump and Irrigation Biopsy Valve System

Trade Name: None at this time.

Classification Name: Endoscope and Accessories

Device Classification: Class II, per 21 CFR 876.1500

Product Code: 78 (OCX)

Predicate Devices:

a. EndoGator Endoscopy Irrigation Pump EGP 100, manufactured by Byrne Medical, Inc. (K060962).

b. ERBE EIP2, (K# unknown)

c. EndoGator System, Byrne Medical, Inc. (K031773)

d. Irrigation Channel Tubing, Byrne Medical, Inc. (K033695)

e. ERBE FLO™ Endoscopy Pump Tubing, manufactured by Byrne Medical, Inc. (K031773, K033695)

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Product Description:
The Irrigation Pump and Irrigation Biopsy Valve System is intended to provide a manual, foot-controlled delivery of fluid from commercially available sterile water bottles to flexible gastrointestinal endoscopes to facilitate the irrigation and lavage of debris within the gastrointestinal tract.

Indication For Use:
The Irrigation Pump and Irrigation Biopsy Valve System is intended to provide a manual, foot-controlled delivery of fluid from commercially available sterile water bottles to flexible gastrointestinal endoscopes to facilitate the irrigation and lavage of debris within the gastrointestinal tract.

The Irrigation Pump is intended as a disposable, manual, foot-controlled, irrigation pump with a bottle cap and back-flow valve that delivers fluid from sterile water bottles.

The Irrigation Biopsy Valve is intended as a disposable, replacement valve that connects the Irrigation Pump to the accessory channel of a flexible endoscope.

Safety and Performance:
Substantial equivalence for the new device was based on design characteristics, a comparison to legally marketed predicate devices, and performance testing. Performance testing consisted of functional bench testing. No components come into direct contact with the patient. All components that come into indirect contact with the patient have a long history of use in medical devices and are biocompatible.

Conclusion:
Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the proposed US Endoscopy Irrigation Pump and Valve System has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Craig L. Moore
General Counsel
United States Endoscopy Group, Inc.
5976 Heisley Road
Mentor OH 44060

NOV - 5 2009

Re: K092461
Trade/Device Name: Irrigation Pump and Irrigation Biopsy Valve System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: August 7, 2009
Received: August 11, 2009

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092461

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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 X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ____
(21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092461