K102855

Summary of Safety and Effectiveness Data

NOV 19 2010

Comparison of features and principles of operation between the Universal Irrigation Solution Hybrid™ and Predicate Devices, Byrne Medical EndoGator®System and Byrne Medical SmartCap® (K092429 and K093665 respectively).

Characteristic				Same
Trade Name	EndoGator®	Endo SmartCap®	Hybrid™	N
Part No.	100130	100145	100605	N
510(k) No.	K092429	K093665	N/A	N
Product Code	FEQ	KOG	KOG	N
Regulation Number	876.1500	876.1500	876.1500	Y
Class	II	II	II	Y
Advisory Committee	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology	Y
Indications for use	The EndoGator® system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.	The Endo SmartCap® is intended to be used with an air or CO_2 and/or pump along with a sterile water source to supply air or CO_2 and sterile water to an endoscope during endoscopic procedures.	The Universal Irrigation Solution Hybrid™ (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO_2 (via aCO_2 pump) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.	Combined
Sterile	Yes	Yes	Yes	Y
Single Use	Yes (24 hr.)	Yes (24 hr.)	Yes (24 hr.)	Y
Compatible Endoscope(s)	Olympus® 140/160/180/240/260 series endoscopes	Olympus® 140/160/180/240/260 series endoscopes	Olympus® 140/160/180/240/260 series endoscopes	Y
Patient Population	Male/Female, Pediatric to Adult	Male/Female Pediatric to Adult	Male/Female, Pediatric to Adult	Y
Reusable or disposable	Disposable	Disposable	Disposable	Y

CONCLUSION:

For irrigation, the 100605 Universal Irrigation Solution Hybrid™ meets or exceeds the performance of the predicate device, the 100130 EndoGator® with the 100115 Auxiliary Water Jet Connector. Thus, the 100605 Hybrid is an effective means of achieving irrigation in GI endoscopic procedures.

When using the 100605 Hybrid the insufflation air flow rate is comparable to that when using the 100145 SmartCap. The system will deliver enough air for insufflation in the time typically used for insufflation. Thus, the 100605 Hybrid is an effective means of achieving insufflation in GI endoscopic procedures.

The lens rinsing performance of the 100605 Hybrid provides a quicker delivery of a blast of water than the predicate 100145 SmartCap device and maintains a sufficient flow of water to rinse debris from the lens. Thus, the 100605 Hybrid is an effective means of achieving lens rinsing in GI endoscopic procedures.

Based on the data results generated with the comparative testing of the subject device compared to the two predicate devices, we have determined, the performance of the 100605 Universal Irrigation Solution Hybrid™is substantially equivalent to that of the combination of the 100145 Endo SmartCap® and 100130 EndoGator® with the 100115 Auxiliary Water Jet Connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Willis
Director of Regulatory Affairs
Byrne Medical, Inc.
3150 Pollok Drive
CONROE TX 77303

NOV 19 2010

Re: K102855
Trade/Device Name: Universal Irrigation Solution Hybrid™
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCX
Dated: September 28, 2010
Received: September 29, 2010

Dear Mr. Willis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

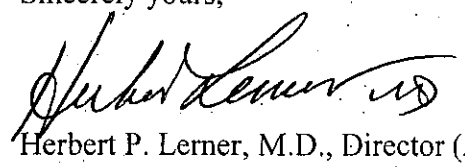
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102855

Indications for Use

NOV 19 2010

510(k) Number (if known) K102855

Device Name: Universal Irrigation Solution Hybrid™

Indications for Use:

The Universal Irrigation Solution Hybrid™ (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO_2 (via aCO_2 pump) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102855