DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Byrne Medical, Inc.
% Mr. Ned Devine
Responsible Third Party
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

JUL 27 2015

Re: K031773
Trade/Device Name: Endo Gator System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated (Date on orig SE ltr): June 6, 2003
Received (Date on orig SE ltr): June 9, 2003

Dear Mr. Devine,

This letter corrects our substantially equivalent letter of June 24, 2003.

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 contact 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. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K 031773

Device Name: Endo Gator System

Indications for use:

The **Endo Gator Irrigation Tubing** is intended as sterile, disposable water bottle tubing with cap and back-flow device that supplies sterile water to irrigation pumps and cauterizing units.

The **Endo Gator Cartridge** is intended as a replacement cartridge for irrigation pumps or cauterizing units for use with the Endo Gator disposable water bottle tubing and cap.

The **Auxiliary Water-port tubing for the Olympus Endoscopes** is intended as a replacement for the existing water-port tubing make by Olympus for the 160 Series of Endoscopes.

Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

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 _____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031773

(Optional Format 1-2-96)

Summary

Assigned 510(k) "K" Number K031773

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

1. Company making the submission:

	Company	Or	Correspondent (contact)
Name: Address:	Byrne Medical, Inc. 13843 Hwy 105 West Suite 317 Conroe, TX 77304		Delphi Consulting Group 11874 South Evelyn Cr. Houston, TX 77071
Telephone: Fax:	800-490-9869 936-588-0392		832-285-9423 775-429-9524
Contact:	Don Byrne President Don@byrnemedical.com		Harvey Knauss Consultant Harvey@delphiconsulting.com

2. Device:

Proprietary Name:	Endo Gator System
Common Name:	Water Bottle Adapter
Classification Name:	Endoscopes and Accessories

3. Predicate Devices:

Device Name	Manufacturer	"K" #
Endo SmartCap™	Byrne Medical	K971125*
UGI-3000B	Meditron	K884836

* Note: Company name changed from Endo Smart Cap Co to Byrne Medical.

4. Classification and Product Code: 21 CFR § 876.1500, Class II, 78 KOG and others.

5. Description:

The Byrne Medical Endo Gator System consists of the following assemblies:

- 100125 – Endo Gator Irrigation Tubing – A sterile, disposable water bottle tubing with cap and back-flow device which supplies sterile water to irrigation pump or cauterizing units. Works only with the Endo Gator Cartridge.

- 100110 – Endo Gator Cartridge – Replacement cartridge for irrigation pump(s) or cauterizing units. The cartridge hub is designed to seat the Endo Gator

Tubing and replace the existing cartridge from the pump manufacturer.

- 100115 – Auxiliary Water-port Tubing for Olympus Scopes – A sterile, disposable water irrigation tubing that replaces the existing water-port tubing made by Olympus for the 160 Series of scopes.

The Endo Gator System tubing sets are sold as a sterile, single patient use devices. It is packaged in a Chevron-style sterile barrier pouch with product label affixed to the clear side of the package. The Endo Gator Cartridge is reusable and is sold not sterile.

6. Indications for Use Statement:

The **Endo Gator Irrigation Tubing** is intended as sterile, disposable water bottle tubing with cap and back-flow device that supplies sterile water to irrigation pumps and cauterizing units.

The **Endo Gator Cartridge** is intended as a replacement cartridge for irrigation pumps or cauterizing units for use with the Endo Gator disposable water bottle tubing and cap.

The **Auxiliary Water-port tubing for the Olympus Endoscopes** is intended as a replacement for the existing water-port tubing make by Olympus for the 160 Series of Endoscopes.

6. Summary of Technological Characteristics and Differences:

The Endo Gator System tubing set consists of a bottle cap/tube set/connector are made of materials that are appropriate for the application, provided sterile for single patient use only. The Endo Gator Cartridge will mount on the irrigator pumps sold by ERBE Endo 100, Pentax EI-400C, Pentax CGI-4000B, Meditron EI-100C, Meditron UGI-3000B and Fujinon JW.. The Endo Gator Cartridge is reusable. The use of the Endo Gator Cartridge becomes a replacement for some predicate device water systems.

Water container(s), which are reused and not maintained properly, may present an infection control risk.

The Endo Gator System and all predicate devices provide water to irrigator pumps or cauterizing units.

7. Contraindications:

The Endo Gator System is not designed, sold or intended for use except as indicated.

No other contraindications are known for this device.

8. Comparison:

The Byrne Medical Endo Gator System has the same device characteristics and the predicate devices. Difference between some systems is providing tubing sets sterile for single patient use.

9. Test Data:

The Byrne Medical Endo Gator System has been subjected to extensive safety, performance, and validations prior to release.

Bench testing was conducted utilizing Meditron UGI-3000B™GI Endoscopy Therapy System and Endolav® Endoscopic Lavage Pumps and EndoGator™ Cartridge and tubing sets.

Flow testing was completed at the minimum and maximum settings of the pump systems. Water flow was measured as a function of total volume over time. In each test the minimum pump setting produced 155 ml/min and maximum produced 650 ml/min with a measurement error of +/- 4%.

Pressure testing – EndoGator™ system was tested to 10 PSI without leaking or any other failure. The pump manufacturer's stated maximum pressure is 4.4 PSI.

10. Conclusions:

The conclusion drawn from these tests is that the Byrne Medical Endo Gator System is equivalent in safety and efficacy to its predicate devices.

DATE: 30 APRIL 2003