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Summary

Assigned 510(k) Number K092429

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

NOV 19 2009

1. Company making the submission and owner:

	Company (**owner**)
Name:	Byrne Medical, Inc. 3150 Pollok Drive Conroe, TX 77303
Telephone:	936-539-0391
Fax:	936-539-2381
Contact:	Don Byrne, President
E-mail:	dbyrne@byrnemedical.com

2. Device:

Proprietary Name:	EndoGator™ System
Common Name:	Water Bottle Adapter
Classification Name:	Endoscopes and Accessories

3. Predicate Device(s):

Device Name	Manufacturer	"K" №
EndoGator™	Byrne Medical, Inc.	K031773
Endoscopic Flushing Pump Model OFP-1	Olympus®	K000948

4. Classification and Product Code:

   21 CFR § 876.1500, Class II, 78 KOG.

5. Description:

   The Byrne Medical EndoGator™ System is composed of the following:
   1) EndoGator™ Irrigation Tubing, and
   2) EndoGator™ Irrigation Accessories

6. Indications for Use Statement:

   The EndoGator™ system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).

7. Summary of Technological Characteristics and Differences:

   The EndoGator™ System consists of a bottle cap/tube set/connector made from materials that are appropriate for the application. The EndoGator™ Cartridge is a replacement for some predicate device water systems.

   The EndoGator™ System and all predicate devices provide water to irrigator pumps or cauterizing units.

   The difference between some systems is the labeling of duration of use.

8. Contraindications:

   The EndoGator™ System is not designed, sold or intended for use except as indicated in labeling.

   No other contraindications are known for this device.

9. Testing:

   The EndoGator™ System has been subjected to extensive safety, performance, and validations prior to release.

   Flow and pressure testing was completed with representative scopes and evaluated based on various pump settings; real-time flow rate data was collected.

10. Conclusions:

    The conclusion drawn from these tests is that the EndoGator™ System is functionally equivalent in safety and efficacy to its predicate device.

_____
Don Byrne, President

_____
Date:

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

Byrne Medical, Inc.
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

NOV 19 2009

Re: K092429
Trade/Device Name: EndoGator™ System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: October 22, 2009
Received: October 23, 2009

Dear Mr. Lehtonen:

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 Statement

EndoGator™ System

K092429

The EndoGator™ system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).

Prescription Use **YES** AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 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, Abdominal,
and Radiological Devices
510(k) Number K092429