

510(k) Summary

Page 1 of 5

11-Oct-11

EasyGlide Ltd.

30 Ha'Ella St.

Kfar Truman, 73150

Israel

Tel – 011-972-528565644

Fax – 011-972-776201003

Official Contact: Izhak Fabian - CEO**Proprietary or Trade Name:** ClearPath Lower GI**Common/Usual Name:** Irrigation/evacuation system**Classification Name/Code:** FDF – endoscope and accessories
21CFR 876.1500
Class 2**Device:** ClearPath Lower GI**Predicate Devices:** K091305 – EasyGlide – ClearPath Lower GI
K093779 - EasyGlide – ClearPath Upper GI**Device Description:**

The proposed modified ClearPath Lower GI is one component of the predicate ClearPath (K091305) which included a number of components:

- Controller
- Tubing Set
- Irrigation set (now referred to as the ClearPath Lower GI)

We are proposing to only modify the ClearPath Lower GI which attaches to a conventional endoscope.

The ClearPath Lower GI includes one suction tube + tip, one irrigation tube + tip, and a sleeve to attach to the endoscope. The ClearPath Lower GI is connected to the ClearPath Controller and the ClearPath Tubing (K091305) and allows for irrigation and evacuation of debris from the colon during an endoscopic procedure. The device can accommodate several sizes and configurations of endoscopes with a change in the attachment ring.

Indications for Use:

The ClearPath Lower GI is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.

510(k) Summary

Page 2 of 5

11-Oct-11

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Patient population:

Individuals undergoing endoscopic procedures.

Environment of Use:

Hospitals, clinics, and doctors' offices.

Performance Testing and Summary:

We have performed bench and animal testing to verify that the ClearPath Lower GI performs as expected in conjunction with standard endoscopes and with the cleared ClearPath controller and tubing K0910305. The tests included:

- Dimensional testing
- Strength testing
- Functional testing
- Mechanical testing
- Compliance with endoscopes

The animal testing evaluated:

- Any sign of dislodgement of the tip from the endoscope during the procedure
- Ease of maneuverability and advance in the colon
- Quality of visibility
- Quality of irrigation
- Any sign of occlusion or interruption to continuous suction.
- Quality of evacuation of feces and other bodily fluid and matter

All testing demonstrated that the modified ClearPath Lower GI disposable performed to its specifications and / or was equivalent to the predicate.

Summary of substantial equivalence:

We demonstrate that the modified ClearPath Lower GI is substantially equivalent to the predicates in design and performance characteristics:

- **Indications** – Similar to predicate K091305: Cleaning of a poorly prepared colon by irrigation and evacuation

510(k) Summary

Page 3 of 5

11-Oct-11

- **Technology** – Identical to predicate K091305: Single use disposable, used with a standard endoscope, works in conjunction with the ClearPath Controller (K091305) to facilitate cleaning of the colon by irrigation and evacuation.
- **Environment of use** – Identical to predicate K091305: Hospitals, clinics, and doctors' offices.
- **Materials** – Materials were either identical to the predicate or shown to comply with ISO 10993-1.
- **Difference** – there are no substantial differences or new features in the proposed device compared to the predicates which raises any new safety or efficacy issue

510(k) Summary

Page 4 of 5

11-Oct-11

Comparative Table - Compares the predicates and the proposed modified device.

	Proposed device	Predicate devices
Device	EasyGlide ClearPath Lower GI	K091305 EasyGlide ClearPath Lower GI
Design	Used as an add-on to standard endoscopes for irrigation and evacuation. Attaches along the endoscope leaving the working channel free. The ClearPath Lower GI is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.	Used as an add-on to standard endoscopes for irrigation and evacuation. Attaches along the endoscope leaving the working channel free. The ClearPath-UGI System is intended for irrigating or cleaning the upper digestive tract and evacuating the irrigation fluid, blood and bile in the upper GI tract during endoscopic procedures.
Indications for use	It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.	It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.
Environment of Use	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.
Prescriptive	Yes, only trained medical personnel	Yes, only trained medical personnel
Principle of operation	Distal attachment to an endoscope, sleeve ensuring attachment along entire length, suction and irrigation tubes running along the endoscope, suction and irrigations heads at the distal tip. Enables irrigation and suction at any time during the procedure without removing any tools which may be inserted in the endoscope's working channel.	Distal attachment to an endoscope, sleeve ensuring attachment along entire length, suction and irrigation tubes running along the endoscope, suction and irrigations heads at the distal tip. Enables irrigation and suction at any time during the procedure without removing any tools which may be inserted in the endoscope's working channel.

K11 3050

510(k) Summary
Page 5 of 5
11-Oct-11

	Proposed device	Predicate devices
Device	EasyGlide ClearPath Lower GI	K093779 EasyGlide ClearPath Upper GI
Accessories	ClearPath Controller and ClearPath Tubing (K091305)	ClearPath Controller and ClearPath Tubing (K091305)
Distal tip design	multi irrigation holes Distal suction hole	multi irrigation holes Distal suction hole
Material	Comply with ISO 10993 Like the predicates, the modified device was tested for compliance and performance under the working conditions as prescribed by the ClearPath Controller (K091305).	Comply with ISO 10993 As detailed in K093779 tests were performed to demonstrate the performance of the device under the working conditions as prescribed by the ClearPath Controller (K091305).
Performance	Comparative animal test compared functionality to that of the predicates	
Disposable	Single patient, use, disposable	Single patient, use, disposable
Packaged	Clean, non-sterile	Clean, non-sterile

K113050



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

EasyGlide Ltd.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

MAY 16 2012

Re: K113050
Trade/Device Name: ClearPath Lower GI
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: April 15, 2012
Received: April 17, 2012

Dear Mr. Dryden:

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.

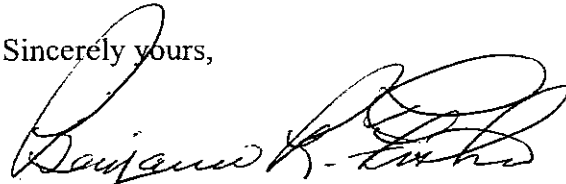
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113050 (To be assigned)

Device Name: ClearPath Lower GI

Indications for Use:

The ClearPath Lower GI is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.


Prescription Use XX
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use ___
(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, Gastro-Renal, and
Urological Devices
510(k) Number K113050