510(k) Summary
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7-Dec-09

K093779

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EasyGlide Ltd.
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Kfar Truman, 73150
Israel

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Official Contact: Izhak Fabian - CEO

Proprietary or Trade Name: ClearPath UGI

MAR - 9 2010

Common/Usual Name: Gastroscope accessory

Classification Name/Code: FDS - endoscope and accessories
CFR 876.1500

Device: ClearPath UGI

Predicate Devices: K091305 – Easy Glide – ClearPath
K060907 – Karl Storz video gastroscope

Device Description:
The ClearPath UGI's main purpose is to improve procedure reliability by improving procedural visualization during endoscopic procedures.

The ClearPath UGI utilizes a suction / irrigation head for the purpose of irrigating or cleaning the upper digestive tract.

The ClearPath UGI is composed of two major units:

- The disposable Irrigator and
- the reusable Control cabinet.

The disposable Irrigator is attached to a standard endoscope by means of silicone bands and does not hinder the endoscope's functionality nor affects the procedure sequence in any way.

The Control cabinet supplies the water flow and vacuum control using a peristaltic pump. The standard medical facility vacuum system is the vacuum source.

Indications for Use:
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.

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

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Patient Population:
Individuals undergoing procedures where a gastroscope is used.

Environment of Use:
Hospitals, clinics, and doctors' offices.

Summary of substantial equivalence:

We have performed testing to demonstrate that the operating performance of the ClearPath UGI is equivalent to the predicate for flow rate, irrigation and vacuum pressures.

	Proposed ClearPath UGI	ClearPath EasyGlide
510(k) number		K091305
Air / Water pressure specifications	Up to 30 Psi	Up to 30 Psi
Flow rate	Up to 300 ml/min	Up to 300 ml/min
Suction specifications	Standard wall suction Approximately 0.5 Bar	Standard wall suction Approximately 0.5 Bar

The proposed ClearPath UGI is only a modification of the predicate ClearPath in that the disposable tubing set is shorter in length and the irrigation tip has been redesigned. No modification have been made to the controller or software.

The ClearPath UGI is viewed as substantially equivalent to the predicate devices because:

Indications –
- Identical to predicate – K060907 – Karl Storz

Technology –
- Identical technology used – K091305 – EasyGlide ClearPath

Materials –
- The materials in patient contact are identical to the predicate device, ClearPath K091305.

Environment of Use –
- Identical to predicate – K091305 – EasyGlide ClearPath

Performance specifications –
- Irrigation pressures, flow rate and suction pressures are identical to the predicate – K091305 EasyGlide ClearPath

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR 9 2010

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

Re: K093779
Trade/Device Name: ClearPath UGI
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated: December 8, 2009
Received: December 9, 2009

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.

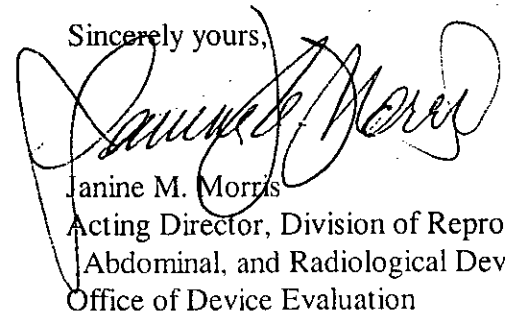
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

510(k) Number: K093779 (To be assigned)

Device Name: ClearPath UGI

Indications for Use:

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.

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, Abdominal,
and Radiological Devices
510(k) Number K093779