



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 30, 2014

Medi-Globe Corporation
Scott Karler
Regulatory Affairs Coordinator
110 West Orion Street, Suite 136
Tempe, AZ 85283

Re: K142258
Trade/Device Name: PolyCatch Retrieval Device
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscope electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: August 8, 2014
Received: August 14, 2014

Dear Scott Karler,

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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 -S

for

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

510(k) Number (if known): TBD

Device Name: PolyCatch Retrieval Device

Indications for Use: The *PolyCatch* Retrieval Device is intended for capture and retrieval of excised polyps, foreign bodies, tissue samples and calculi during flexible or rigid endoscopy procedures.

Prescription Use _____
(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)

510(k) SUMMARY

Date of Preparation: 08/06/2014

A. Submitter Information:

Submitter's Name: Medi-Globe Corporation

Submitter's Address: 110 West Orion Street #136
Tempe, Arizona 85283

Contact Person: Scott Karler

Contact Person's Telephone Number: (480) 897-2772 ext. 208

Contact Person's FAX Number: (480) 897-2878

Contact Person's Email Address: skarler@mediglobe.com

B. Proposed Device Information

- Trade Name: *PolyCatch* Retrieval Device
- Common Name: Snare, Flexible
- Classification Name: Endoscopic electro-surgical unit and accessories 21 CFR 876.4300
- Product Code: FDI, GCJ

C. Predicate Device:

- Trade Name: *Roth Net* Retriever
- Manufacturer: United States Endoscopy Group, Inc.
- Clearance Number: K122462
- Common Name: Snare, Flexible
- Classification Name: Endoscopic electro-surgical unit and accessories 21 CFR 876.4300
- Product Code: FDI, GCJ

D. Device Description:

The *PolyCatch* Retrieval Device is a complete one-piece device for retrieval of polyps and foreign bodies from the gastrointestinal and respiratory tracts and is a disposable instrument intended for single patient use only. The *PolyCatch* Retrieval Device is used through the working channel of a legally marketed endoscope. The *PolyCatch* Retrieval Device consists of a handle, outer sheath and a snare wire/loop to which a non-Latex pouch is attached. As the snare wire is advanced from of the outer sheath of the device, it expands to its full circumference thereby deploying the non-Latex pouch. The pouch can then be manipulated by the clinician to engage a polyp or foreign body. After the polyp or foreign body is captured within the pouch the handle is used to draw the snare wire and pouch back against the device sheath. The endoscope along with the *PolyCatch* is then removed together from the patient to complete the retrieval procedure.

E. Intended Use:

The *PolyCatch* Retrieval Device is intended for capture and retrieval of excised polyps, foreign bodies, tissue samples and calculi during flexible or rigid endoscopy procedures.

F. Technological Characteristics Summary:

The *PolyCatch* Retrieval Device is very similar in design to a non-electric polypectomy snare, with the exception that it features a pre-formed pouch manufactured from a Thermoplastic Polyurethane, (TPU). The pouch is fixed to the snare wire using a medical grade adhesive. The device handle allows the pouch to be advanced out of the device catheter in order to capture the intended tissue or foreign body. Once the tissue/foreign body has been captured within the pouch, the 3-ring handle is used to draw the pouch back towards the device catheter, which then closes around the tissue/foreign body, allowing the device along with the endoscope to be removed from the patient.

G. Non-Clinical Performance Data:

Design verification data and biocompatibility testing has demonstrated that the proposed *PolyCatch* Retrieval Device is safe and effective. Performance testing was conducted in accordance with the applicable Guidance Document titled “Guidance for the content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology. Additionally, bench performance testing was conducted using a specially designed test fixture intended to simulate actual device use of the *PolyCatch* Retrieval Device.

H. Conclusions of Non-Clinical Performance Data:

Medi-Globe Corporation has demonstrated that the proposed *PolyCatch* Retrieval Device is as safe and effective as the predicate device, (*Roth Net Retriever*, K122462). The *PolyCatch* Retrieval Device is considered to have the same intended use, diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the predicate device, (*Roth Net Retriever*, K122462).