DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 18, 2016

Medi-Globe Corporation
Scott Karler
Regulatory Affairs Coordinator
7850 South Hardy Drive, Suite. 112
Tempe, AZ 85284

Re: K153264
Trade/Device Name: EasyPass Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCY
Dated: April 7, 2016
Received: April 13, 2016

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153264

Device Name

EasyPass Guidewire

Indications for Use *(Describe)*

The EasyPass Guidewire is used for selective cannulation of the biliary ducts including, but not limited to the common bile duct, cystic duct, and right and left hepatic ducts. The EasyPass guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Date of Preparation: 11/09/2015

A. Submitter Information:

Medi-Globe Corporation
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Tempe, Arizona 85284

Contact Person: Scott Karler
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B. Proposed Device Information:

- Trade Name: *EasyPass Guidewire*
- Common Name: Endoscopic Guidewire, Gastroenterology-Urology
- Classification Name: Endoscope and Accessories 21 CFR876.1500
- Product Code: OCY

C. Predicate Device:

- Trade Name: *Taxi* Endoscopic Guidewire
- Manufacturer: Lake Region Manufacturing, Inc.
- Clearance Number: K081708
- Common Name: Endoscopic Guidewire, Gastroenterology-Urology
- Classification Name: Endoscope and Accessories 21 CFR876.1500
- Product Code: OCY

D. Device Description:

The *EasyPass* Guidewire consists of a Nitinol core wire with a proximal 2-color spiral patterned PTFE jacket and a copolymer distal section. The distal stainless steel spring section of the guidewire provides flexibility and incorporates a hydrophilic coating. The *EasyPass* Guidewire is a sterile packed, disposable instrument intended for single-patient use only.

E. Indications for Use:

The *EasyPass* Guidewire is used for selective cannulation of the biliary ducts including, but not limited to the common bile duct, cystic duct, and right and left hepatic ducts. The EasyPass guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

F. Technological Characteristics Summary:

The *EasyPass* Guidewire is a 2-color spiral patterned guidewire used in endoscopic procedures. It is comprised of a Nitinol core wire with a 2-color PTFE jacket as a visualization aid during use of the guidewire. The distal section of the EasyPass Guidewire consists of a stainless steel spring encased in a polymer jacket and is hydrophilically coated. The predicate device, *Taxi* Endoscopic Guidewire, (K081708) incorporates the same design, intended use, diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the proposed, *EasyPass* Guidewire. There are no technological differences when comparing the proposed *EasyPass* Guidewire to the predicate device.

G. Non-Clinical Performance Data:

Design verification data and biocompatibility testing has demonstrated that the proposed *EasyPass Guidewire* meets the same performance requirements and is as safe and effective as predicate device, *Taxi* Endoscopic Guidewire, (K081708).

The following non-clinical performance tests were conducted on the proposed EasyPass Guidewire:

<u>Biocompatibility testing per ISO 10993:</u>
Cytotoxicity
Irritation
Sensitization

USP Class VI Testing performed on color additives

<u>Bench/performance testing consisted of:</u>
Fracture Test
Bend Test
Friction Test
Scratch Test
Tensile Test
Radiographic Image Test

H. Conclusions of Non-Clinical Performance Data:

Medi-Globe Corporation has demonstrated that the proposed *EasyPass Guidewire* is as safe and effective as the predicate device, (*Taxi* Endoscopic Guidewire, K081708). The *EasyPass Guidewire* 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, (*Taxi* Endoscopic Guidewire, K081708*).* No clinical testing was relied on for evaluation of the proposed device.