K061684
PG. 1 OF 2

JUN 27 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

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

B.Device Name:
Medi-Globe Rota-Cut® Sphincterotome

C.Predicate Devices:
GIP/Medi-Globe Papillotome (K943629/A)

Boston Scientific
Needle Knife Sphincterotome (K973826)
AutoTome RX Model (K013153)

Wilson-Cook Medical
Needle Knife Papillotome (K972674)
Tri-Tome Select Plus (K033203)

D.Device Description:

The proposed Medi-Globe Rota-Cut® Sphincterotome is available in single, double or triple lumen models and allows incremental, rotational orientation of the distal catheter tip and cutting wire. Device models are compatible with either .021 or .035" guide wires and allow simultaneous injection of contrast medium during use.

E.Intended Use:

The proposed Medi-Globe Rota-Cut® Sphincterotome is used for transendoscopic cannulation of the biliary system and sphincterotomy of the Papilla of Vater and/or Sphincter of Oddi.

F.Technological Characteristics Summary:

The Rota-Cut® Sphincterotomes are substantially equivalent to sphincterotomes currently cleared for sale in the United States. The proposed Rota-Cut® sphincterotomes are manufactured from similar medical grade plastics and stainless steel as the predicate devices.

G.Performance Data:

Design verification tests have demonstrated that the proposed Rota-Cut® sphincterotomes meet the same performance standards and biocompatibility requirements and is as safe and effective as the currently cleared GIP/Medi-Globe device, (K943629/A). The Rota-Cut® Sphincterotome is considered to have the same intended diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the GIP/Medi-Globe predicate devices.

Prepared by: Scott Karler
Date: April 6, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2006

Medi-globe® Corporation
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K061684
Trade/Device Name: Rota-Cut® Sphincterotome
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: June 14, 2006
Received: June 15, 2006

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~TBD~~ K061684

Device Name: Medi-Globe Rota-Cut® Sphincterotome

Indications for Use: The Medi-Globe Rota-Cut® Sphincterotome is intended for transendoscopic cannulation of the Biliary system and sphincterotomy of the Papilla of Vater an/or the Sphincter of Oddi.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061684