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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

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

B. Device Name:
Medi-Globe SonoTip II 25-gauge Ultrasound Needle System

C. Predicate Devices:
Medi-Globe SonoTip II Ultrasound Needle System (K070129)

Medi-Globe SonoTip II Ultrasound Needle System (K051247)

Wilson-Cook Ultrasound Biopsy Needle (K013356)

D. Device Description:

The Medi-Globe SonoTip II 25-gauge Ultrasound Needle System is a complete one-piece needle system for Fine Needle Aspiration and is a disposable instrument intended for single patient use only.

E. Intended Use:

The Medi-Globe SonoTip II 25-gauge Ultrasound Needle System for Fine Needle Aspiration (FNA), is used in conjunction with various legally marketed, FDA registered Ultrasound Endoscopes. The SonoTip II 25-gauge Needle System is used for ultrasonically guided, fine needle aspiration (FNA) of submucosal and extra-luminal lesions of the gastrointestinal tract (i.e., pancreatic masses, mediastinal masses, peri-pancreatic masses and lymph nodes).

F. Technological Characteristics Summary:

The Medi-Globe SonoTip II Ultrasound Needle System utilizes endoscopic ultrasound technology which, when used with an ultrasound endoscope, allows the user to ultrasonically guide the biopsy needle to its intended target within or adjacent to the gastrointestinal system.

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G. Performance Data:

Design verification data has demonstrated that the proposed Medi-Globe SonoTip II 25-gauge Ultrasonic Needle System meets the same performance requirements and is as safe and effective as Medi-Globe's currently cleared predicate device. The 25-gauge SonoTip II Needle System is considered to have the same intended diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the predicate Medi-Globe SonoTip II Ultrasound Needle System (K070129).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2009

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

Re: K083802
Trade/Device Name: SonoTip II 25-Gauge Ultrasound Needle System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: December 18, 2008
Received: December 22, 2008

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

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

510(k) Number (if known): TBD K083807

Device Name: *SonoTip II* 25-gauge Ultrasound Needle System

Indications for Use: The SonoTip II 25-gauge Ultrasound Needle System is used in conjunction with various legally marketed, FDA registered Ultrasound Endoscopes. The SonoTip II Needle System is used for ultrasonically guided fine needle aspiration, (FNA) of submucosal and extra-luminal lesions of the Gastrointestinal tract (i.e., pancreatic masses, mediastinal masses, peri-pancreatic masses and lymph nodes.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083807