K070129

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

JAN 31 2007

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 SonoTip II Ultrasound Needle System

C. Predicate Devices:
GIP/Medi-Globe GI Ultrasound Needle System (K990220)

Medi-Globe SonoTip II Ultrasound Needle System (K051247)

D. Device Description:

The SonoTip II Endoscopic 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. A feature allowing the length of the outer metal sheath to be adjusted has been incorporated into the SonoTip II needle system. This feature provides the user with the ability to precisely adjust the working length of the instrument relative to the endoscope being used.

E. Intended Use:

The SonoTip II Ultrasound Needle System for Fine Needle Aspiration (FNA), 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).

F. Technological Characteristics Summary:

The 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.

G. Performance Data:

Design verification data has demonstrated that the modified SonoTip II Ultrasonic Needle System meets the same performance requirements and is as safe and effective as the currently cleared predicate device. The modified 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 (K051247).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Medi-Globe Corporation
c/o Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

JAN 3 1 2007

Re: K070129
Trade/Device Name: Medi-Globe SonoTip II Ultrasound Needle System
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: January 12, 2007
Received: January 16, 2007

Dear Mr. Devine:

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~~ K070129

Device Name: *SonoTip II* Ultrasound Needle System

Indications for Use: The SonoTip II 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)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070129