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510(k) Summary

GIP/Medi-Globe Needle System for Ultrasonic FNA

This 510(k) summary of safety and effectiveness is being submitted in accordance to with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

Device Name :	GIP/Medi-Globe Needle System for Ultrasonic FNA
Common/User Name :	Ultrasound Needle for Ultrasonic Fine Needle Aspiration
Classification :	Gastro-Urology Biopsy Instruments; 21 CFR 876-1075
Proprietary Name :	Various Brand Names of Aspiration Needles
Predicate Device :	GIP/Medi-Globe GI Ultrasound Needle System K935844
Prepared & Submitted By :	Michelle L. Fields Project Manager Medi-Globe Corporation 6202 S. Maple Avenue, Suite 131 Tempe, Arizona 85283 (602) 897-2772
Preparation Date :	January 7, 1999
Indications for Use :	The GIP/ Medi-Globe Needle System for Ultrasonic FNA is specifically designed 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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Ms. Michelle L. Fields
Project Manager
Medi-Globe® Corporation
6202 S. Maple Avenue, #131
Tempe, AZ 85283

Re: K990220
GIP/Medi-Globe Ultrasound Needle System
Dated: January 7, 1999
Received: January 13, 1999
Regulatory Class: II
21 CFR 876.1075/Procode: 78 FCG

Dear Ms. Fields:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990220

Device Name: GIP/Medi-Globe Ultrasound Needle System

Indications for Use:

The Medi-Globe Needle System for Ultrasonic FNA is designed to be used with the Pentax FG32, 34, 36, 38 UA ultrasound endoscopes 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).

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990220