K061222
Page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JUL - 3 2006

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:
Injectra Injection Needle

C. Predicate Devices:

GIP/Medi-Globe Sclerotherapy Needle, (K955558)

D. Device Description:

The *Injectra* Injection Needle is a device that is used to deliver solutions into tissues of the digestive tract through the accessory channel of a legally marketed endoscope.

E. Intended Use:

The *Injectra* Injection Needle is a complete one-piece injection needle intended for endoscopic injection of solutions such as sclerosing agents into tissues of the digestive system to control bleeding and for injection of saline as a procedural aid in endoscopic polypectomy procedures. The *Injectra* Injection Needle is a disposable device and is intended for single patient use only.

K061222
Page 2 of 2

F. Technological Characteristics Summary:

Medi-Globe believes that the proposed *Injectra* Injection Needle is substantially equivalent to the currently cleared GIP/Medi-Globe Sclerotherapy Needle, (K955558) in device function and overall design. The additional indications are also consistent with currently cleared devices marketed by Boston Scientific Corporations Interject™ Injection Needle Therapy Needle, (K012864).

G. Performance Data:

Design verification data has demonstrated that the *Injectra* Injection Needle meets the same performance requirements and is as safe and effective as the predicate GIP/Medi-Globe device, (K955558). Biological testing has been performed on the proposed *Injectra* Injection Needle due to the change in indirect patient contacting materials. The results have indicated that the *Injectra* Needle does not affect the biological safety of the patient.

Prepared by: Scott Karler
Date: May 1, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 3 2006

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

Re: K061222
Trade/Device Name: *Injectra* Injection Needle
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: May 1, 2006
Received: May 2, 2006

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 (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): K061222

Device Name: *Injectra* Injection Needle

Indications for Use: The Medi-Globe® *Injectra* Needle is used in conjunction with various legally marked, FDA registered flexible endoscopes. The *Injectra* Needle is used for endoscopic injection of solutions into tissues of the digestive system and injection of saline as a procedural aid in endoscopic polypectomy procedures.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061222