MEDIVATORS®
A Cantel Medical Company

EndoGator Advantage CO2 Insufflator EGA-501

JUN 2 0 2012

510(k) Summary

Manufacturer: Medivators
(formerly Byrne Medical, A Minntech Corporation Business Group)

Address: 3150 Pollok Dr.
Conroe, TX 77303
USA

Official Contact: Brent Geiger, MS, RAC
International RA Manager
bgeiger@medivators.com
763-553-3345

Trade Name: EndoGator Advantage CO2 Insufflator EGA-501
Common Name: Endoscopic Insufflator
Classification Name: Insufflator, automatic carbon-dioxide for endoscope
Product Code: FCX, Gastroenterology/Urology
Device Class: II
Regulation No.: 876.1500

Date Prepared: June 8, 2012

Predicate Device: E-Z-EM Endoscopic CO2 Regulator
510(k) Number: K053008

Medivators has provided the following information to the U.S. Food and Drug Administration to support the substantial equivalence determination of the subject EndoGator Advantage CO2 Insufflator to the predicate E-Z-EM Endoscopic CO2 Regulator device currently cleared for commercial distribution in the United States.

Device Description

The EndoGator Advantage CO2 Insufflator EGA-501 is indicated to use CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope. It is intended to be used for delivery of CO2 via an endoscope system to provide improved visualization during gastrointestinal endoscopic procedures.

The EndoGator Advantage CO2 Insufflator operates by receiving CO2 from a pressurized source and regulating it down to a lower pressure and flow rate by means of a two-stage pressure regulator and flow restrictor system. The device controls delivery of CO2 to an endoscope system for eventual use as a distention media in endoscopic procedures.

The output flow rate is user adjustable and can be set at low, medium or high settings. Flow is controlled by a system of electrical solenoid flow restrictors. The device contains a pressure relief safety valve as a redundant safety backup to the pressure regulator system.

MEDIVATORS®
A Cantel Medical Company

The EndoGator Advantage CO2 Insufflator includes a CO2 warming feature that allows the clinician to modulate and control delivery of CO2 that has been warmed to a target temperature of 37°C. The insufflator warms CO2 using a flow-through heating element with built-in dual redundant resistance temperature detector sensors and an added safety thermostat.

The device design also contains an optional feature that allows for connection of an externally attachable water bottle warmer accessory. The water bottle warmer system design is identical to the design used in the related Endogator Advantage Irrigation Pump EGA-500 (K113119). The feature was included in the insufflator design to provide the user with the option for warm water irrigation in the event that they choose to use an alternative irrigation pump to the EGA-500.

Indications for Use

The EndoGator Advantage CO2 Insufflator is designed to use CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The EndoGator Advantage CO2 Insufflator contains a CO2 warming feature that allows the clinician to modulate and control delivery of CO2 to the patient that has been warmed to a target temperature 37°C.

Comparison to Other Devices in Commercial Distribution in the United States

Both the subject and predicate devices have the same intended use and general performance as endoscopic CO2 insufflators. They are both intended to regulate and administer CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope. The EndoGator Advantage CO2 Insufflator has the same basic indications for use as the predicate device, but the indications do differ in that the subject device contains a CO2 warming feature that allows the clinician to modulate and control delivery of CO2 to the patient that has been warmed to a target temperature of 37°C while the predicate does not. The added CO2 warming feature does not present additional risks as it is simply being used to introduce CO2 that is heated to approximately the same target temperature as the surrounding tissues in gastrointestinal (GI) tract.

Certain other performance and functional characteristics of the subject device such as user selectable modes of operation, unit displays/controls, output pressure, pressure relief setting and optional water warming capability do differ slightly from the predicate, however evaluation and testing has been performed to demonstrate that the differences do not impact device safety or performance, and any risks associated with the differences are acceptable.

Summary of Non-Clinical Performance Data

Medivators has performed bench testing to support the substantial equivalence of the EndoGator Advantage CO2 Insufflator to the predicate E-Z-EM Endoscopic CO2 Regulator cleared via K053008 for commercial distribution in the United States. The following types of data were provided to FDA to support substantial equivalence and demonstrate that the device performs consistently, reliably and safely as intended:

- Simulated insufflation performance comparison
- CO2 flow and pressure comparison testing
- CO2 heater performance
- CO2 heater performance with flow shut-off

MEDIVATORS®
A Cantel Medical Company

- CO2 temperature and flow through endoscope system
- CO2 pressure relief valve performance
- Risk analysis
- Electrical safety IEC 60601-1
- Electromagnetic compatibility IEC 60601-1-2
- Water bottle warmer performance

Conclusion

Medivators has provided the appropriate premarket notification and supporting safety and performance information in the form of a 510(k) submission. Based on the information provided, we believe that the EndoGator Advantage CO2 Insufflator EGA-501 is substantially equivalent to the E-Z-EM Endoscopic CO2 Regulator device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Brent Geiger, MS, RAC
International RA Manager
Medivators (formerly Byrne Medical,
A Minntech Corporation Business Group)
14605 28th Avenue North
MINNEAPOLIS MN 55442

JUN 20 2012

Re: K113310
Trade/Device Name: EndoGator® Advantage CO_2 Insufflator, Model EGA-501
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCX
Dated: June 11, 2012
Received: June 12, 2012

Dear Mr. Geiger:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K113310

Device Name: EndoGator® Advantage CO2 Insufflator

Indications for Use:

The EndoGator® Advantage CO2 Insufflator is designed to use CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

Prescription Use ___X___ (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, Gastro-Renal, and Urological Devices
510(k) Number K113310