Submission Date: 06 June 2011

Submitter: Bracco Diagnostics, Inc.
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Trade Name: Bracco Diagnostics, Inc. CO₂MPACT ENDOSCOPIC INSUFFLATOR™

Common Name: CO₂ Insufflator

Classification Name: Endoscope and accessories

Classification Regulation: 21 CFR §876.1500

Product Code: FCX

Substantially Equivalent Devices: New BDI Model

Predicate
510(k) Number
K053008

Predicate Manufacturer / Model
E-Z-EM, Inc. (now BDI)
/ CO₂Efficient Endoscopic Insufflator

K081173

Olympus Medical Systems, Corp. / UCR
Endoscopic CO₂ Regulation Unit
Device Description: The Bracco Diagnostics, Inc. (BDI), CO₂MPACT ENDOSCOPIC INSUFFLATOR™ (CO₂MPACT) is designed to use CO₂ as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope. The BDI CO₂MPACT regulates CO₂ flow rate and pressure during the insufflation process.

The BDI CO₂MPACT allows the physician to modulate and control the CO₂ to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Consistent with the predicate devices, the BDI CO₂MPACT is used to administer CO₂ to the patient for distention purposes. For this application, the actual displacement of CO₂ to the patient through the endoscope is controlled by the clinician modulating an “air-water” valve on the endoscope. The BDI CO₂MPACT only provides source pressure and flow to the endoscope in a similar manner to the predicates BDI CO₂Efficient Endoscopic Insufflator (K053008) and Olympus UCR Endoscopic CO₂ Regulation Unit (K081173), or the internal air pump included within the endoscope light source.

Intended Use: The Bracco Diagnostics, Inc. (BDI) CO₂MPACT ENDOSCOPIC INSUFFLATOR™ is designed to use CO₂ as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The BDI CO₂MPACT ENDOSCOPIC INSUFFLATOR™ allows the physician to modulate and control the CO₂ to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Technology Comparison: The BDI CO₂MPACT employs the same technological characteristics as the predicate devices.
Summary of Performance Testing:

**Performance Testing**  
The BDI CO₂MPACT was tested for performance in accordance with internal requirements.  
Test results indicated that the BDI CO₂MPACT complies with its predetermined specification and with the applicable Standards.

**Biocompatibility Verification**  
Patient contact materials within the BDI CO₂MPACT and the tubing set was verified for performance in accordance with:


Verification results indicated that the materials comply with predetermined specifications.

**Software Testing**  
Software device modifications made to the BDI CO₂MPACT were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02; and*

Test results indicate that the BDI CO₂MPACT complies with its predetermined specification.
Special 510(k) Premarket Notification
Bracco Diagnostics, Inc.
CO2MPACT ENDOSCOPIC INSUFFLATOR™
510(k) Summary

**Electrical Safety Testing**
The BDI CO2MPACT was tested for patient safety in accordance with:

Test results indicated that the BDI CO2MPACT complies with applicable Standards.

**Electromagnetic Compatibility Testing**
The BDI CO2MPACT was tested for EMC in accordance with:

Test results indicated that the BDI CO2MPACT complies with applicable Standards.

**Performance Testing – Bench**
The BDI CO2MPACT was tested for performance in accordance with internal requirements.

Test results indicated that the BDI CO2MPACT complies with applicable Standards.

**Conclusion**
Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the BDI CO2MPACT. The results of these activities demonstrate that the BDI CO2MPACT is safe and effective when used in accordance with its intended use and labeling.

Therefore, the BDI CO2MPACT is considered substantially equivalent to the predicate device.
Dear Ms. Alexander:

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
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,

[Signature]

Herbert P. Lerner, M.D., Director (Acting)
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): K 111448

Device Name: Bracco Diagnostics, Inc. CO2MPACT ENDOSCOPIC INSUFFLATORTM

Indications for Use: The Bracco Diagnostics, Inc. (BDI) CO2MPACT ENDOSCOPIC INSUFFLATORTM is designed to use CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The BDI CO2MPACT ENDOSCOPIC INSUFFLATORTM allows the physician to modulate and control the CO2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Prescription Use X AND/OR Over-The-Counter Use (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 K 111448