510(k) Summary

Submission Date:	26 September 2012
Submitter:	Bracco Diagnostics, Inc. 107 College Road Princeton, NJ 08540 USA
Submitter and Official Contact:	Bracco Diagnostics Inc. 532 Broadhollow Road, Suite 126 Melville, NY 11747 Ms. Tracey Alexander Director Regulatory Affairs Phone: +1 (609) 524-2865 Fax: +1 (631) 847-3904 Email: tracey.alexander@diag.bracco.com
Trade Name:	Bracco Diagnostics, Inc. CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET
Common Name:	Tubing Set
Classification Name:	Endoscope and accessories
Classification Regulation:	21 CFR §876.1500
Product Code:	FCX, FDS

AUG 06 2013

Substantially Equivalent Devices:

BDI Model	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
Bracco Diagnostics, Inc. CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET	K053008	E-Z-EM, Inc. (now BDI) CO_2 Efficient Endoscopic Insufflator
	K954451	Olympus America, Inc. EVIS 140 System (MH-970 Water Container Accessory)

Device Description:

The Bracco Diagnostics Inc. (BDI) CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET (ILTS) is intended for use with BDI CO_2 Endoscopic Insufflators and OEM endoscope systems, in this specific case the Olympus® 140, 160, 180, and 190 series endoscopes.

The ILTS is supplied sterilized using Gamma radiation to a Sterility Assurance Level (SAL) of 10^{-6}.

The ILTS is individually packaged At the time of this submission, accelerated aging tests confirmed a one (1) year shelf life.

Intended Use:

The CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET is intended to connect a CO_2 source (insufflator), and a sterile water source (water bottle), to an endoscope to supply CO_2 during gastrointestinal endoscopic procedures.

Technology Comparison:

The ILTS employs the same technological characteristics as the predicate devices.

Characteristic Comparisons:

	E-Z-EM, Inc. (Bracco Diagnostics, Inc.) CO_2 ENDOSCOPIC INSUFFLATOR Tubing Set (K053008)	*Olympus MH-970 Water Container (Accessory within the Olympus EVIS 140 Video Endoscopy System) (K954451)*	*Bracco Diagnostics, Inc. CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET*
Intended Use	The CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET is intended to be used with a CO_2 source and insufflator, along with a sterile water source, to supply CO_2 and sterile water to an endoscope during gastrointestinal endoscopic procedures.	The Olympus MH-970 Water Container is intended to be used with a CO_2 source and insufflator, along with a sterile water source, to supply CO_2 and sterile water to an endoscope during endoscopic procedures.	The CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET is intended to connect a CO_2 source (insufflator), and a sterile water source (water bottle), to an endoscope to supply CO_2 during gastrointestinal endoscopic procedures.
Compatibility	Connects to OEM endoscope systems that are equipped with an external CO_2 luer connector.	Connects to Olympus® 140, series endoscopes.	Same for both predicates
Sterility Method	Non-sterile.	Glutaraldehyde; Autoclaveable (Provided non-sterile)	Radiation (Provided sterile)
Sterility Assurance Level	Not applicable	Unknown	10^{-6}

Disposable or Reusable	Disposable	Reusable	Disposable
Packaging	Poly bag	Unknown	10" x 14" Tyvek®, peelable pouch or similar
Shelf-Life	Six (6) years	Unknown	One (1) year initially

Performance Testing:

Sterilization

The ILTS is gamma radiation sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standards:

- *ISO 11137-1: 2006, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization;* and
- *ISO 11137-2:2006 (currently under revision), Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.*

Verification results indicate that the ILTS complies with the standards.

Shelf-Life

The ILTS is sterilized and its packaging was validated in accordance with the following standards:

- *ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems; and*
- *ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

Verification results indicate that the ILTS complies with the standards.

Biocompatibility

ILTS patient contact materials were verified in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicated that the ILTS patient contact materials comply with the standard.

Performance Testing – Bench

The ILTS was tested for performance in accordance with its predetermined specifications. Testing included:

- Device compatibility;
- Usability;
- Environmental;
- Delivery flow rate;
- Delivery pressure;
- Leakage;
- Mechanical integrity;
- Shipping and transportation; and
- Labeling.

Test results indicate that the ILTS complies with its predetermined specification.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the ILTS. The results of these activities demonstrate that the ILTS is safe and effective when used in accordance with its intended use and labeling.

Therefore, the ILTS is considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 6, 2013

Bracco Diagnostics, Inc.
% Tracey Alexander
Director Regulatory Affairs
532 Broadhollow Road, Suite 126
Melville, NY 11747

Re: K123047
Trade/Device Name: Bracco Diagnostics, Inc. CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX, FDS
Dated: July 12, 2013
Received: July 26, 2013

Dear Tracey 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 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 contact 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. 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,

Herbert P. Lerner -S

for

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): K 123047

Device Name: Bracco Diagnostics, Inc. CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET

Indications for Use: The CO_2 ENDOSCOPIC INSUFFLATOR IN LINE TUBING SET is intended to connect a CO_2 source (insufflator), and a sterile water source (water bottle), to an endoscope to supply CO_2 during gastrointestinal endoscopic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123047