

510(k) Premarket Notification
Bracco Diagnostics Inc.
PROTOCO₂L Touch Colon Insufflator
510(k) Summary

FEB 14 2014

Submission Date: 12 July 2013

Submitter: Bracco Diagnostics Inc.
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831 USA

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Trade Name: Bracco Diagnostics Inc. PROTOCO₂L Touch Colon Insufflator

Common Name: CO₂ Colon Insufflator

Classification Name: Endoscope and accessories

Classification Regulation: 21 CFR §876.1500

Product Code: FCX

Substantially Equivalent Devices:

<i>New BDI Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
Bracco Diagnostics Inc. PROTOCO ₂ L Touch Colon Insufflator	K030854	E-Z-EM, Inc. (now BDI) / PROTOCO ₂ L Colon Insufflator with Performance Improvements
	K013219	E-Z-EM, Inc. (now BDI) / PROTOCO ₂ L Colon Insufflator.

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Device Description: The Bracco Diagnostics Inc. (BDI) PROTOCO₂L Touch Colon Insufflator (PROTOCO₂L Touch) administers and regulates CO₂ as a distention media to the colon during Computed Tomography Colonography (CTC or Virtual Colonoscopy). Insufflation during CTC is used to distend the colon with uniform pressure in order to properly present the colon during the given diagnostic procedure.

The PROTOCO₂L Touch consists of two (2) components:

- (1) the Colon Insufflator, and
- (2) the disposable, non-sterile Administration Set.

Intended Use: The PROTOCO₂L Touch Colon Insufflator administers and regulates CO₂ as a distention media to the colon during Computed Tomography Colonography (CTC or Virtual Colonoscopy).

Technology Comparison: The PROTOCO₂L Touch employs the same technological characteristics as the predicate devices.

Characteristic Comparisons:

Indications for Use

Design Approach

Anatomical Sites

Location of Unit

	<i>E-Z-EM, Inc. PROTOCO₂L Colon Insufflator Model 6400</i>	<i>E-Z-EM, Inc. PROTOCO₂L Colon Insufflator with Performance Improvements</i>	<i>Bracco Diagnostics Inc. PROTOCO₂L Touch Colon Insufflator</i>
	The E-Z-EM PROTOCO ₂ L COLON Insufflator administers and regulates carbon dioxide (CO ₂) as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.	The E-Z-EM PROTOCO ₂ L COLON Insufflator administers and regulates carbon dioxide (CO ₂) as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.	The PROTOCO ₂ L Touch Colon Insufflator is designed to administer and regulate CO ₂ as a distention media to the colon during Computed Tomography Colonography (CTC or Virtual Colonoscopy).
	Electro-mechanical pneumatic system to regulate CO ₂ flow and pressure.	Electro-mechanical pneumatic system to regulate CO ₂ flow and pressure.	Same as predicates
	Rectal administration of CO ₂ via enema tip or catheter lumen	Rectal administration of CO ₂ via enema tip or catheter lumen	Same as predicates.
	Located next to CT gantry.	Located next to CT gantry.	Same as predicates.

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Summary of Performance Testing:

Sterilization and Shelf-Life

The PROTOCO₂L Touch is not shipped sterile, and is not intended to be sterilized by the user. Additionally, the PROTOCO₂L Touch does not have a shelf life. Therefore, this section is not applicable.

Biocompatibility

Patient contact materials within the PROTOCO₂L Touch tubing set were verified in accordance with:

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

Results indicated that the materials comply with the applicable Standard.

Software Testing

The PROTOCO₂L Touch software was designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with internal requirements and the following guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the PROTOCO₂L Touch complies with its predetermined specifications and the guidance documents.

Electrical Safety Testing

The PROTOCO₂L Touch was tested for patient safety in accordance with the following standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; and*
- *UL 60601-1: 2006, Medical Electrical Equipment, Part 1: Particular Requirements for Safety.*

Test results indicated that the PROTOCO₂L Touch complies with the applicable Standards.

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**Electromagnetic
Compatibility
Testing**

The PROTOCO₂L Touch was tested for EMC in accordance with the following standard:

- *IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests*

Test results indicated that the PROTOCO₂L Touch complies with the applicable Standard.

**Performance Testing
– Bench**

The PROTOCO₂L Touch was tested for performance in accordance with internal requirements and the following standard.

- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices; and*
- *ISTA Procedure 3A – 2008, Packaged-Products for Parcel Delivery System Shipments 70kg (150lb) or Less (standard, small, flat or elongated)*

Test results indicated that the PROTOCO₂L Touch complies with internal requirements and the applicable Standard.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the PROTOCO₂L Touch. The results of these activities demonstrate that the PROTOCO₂L Touch is safe and effective when used in accordance with its intended use and labeling.

Therefore, the PROTOCO₂L Touch is considered substantially equivalent to the predicate device.



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

February 14, 2014

Bracco Diagnostics, Inc.
Tracey Alexander
Director Regulatory Affairs
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831

Re: K132192
Trade/Device Name: PROTOCO₂L Touch Colon Insufflator
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: January 16, 2014
Received: January 22, 2014

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/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" (21 CFR 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 132192

Device Name: PROTOCO₂L Touch Colon Insufflator

Indications for Use: The PROTOCO₂L Touch Colon Insufflator administers and regulates CO₂ as a distention media to the colon during Computed Tomography Colonography (CTC or Virtual Colonoscopy).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(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
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