K090879

SECTION 1. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

JUL 23 2009

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for Insu*flow*® CO_2lonShield™.

SUBMITTER'S NAME:	LEXION Medical LLC
ADDRESS:	5000 Township Parkway
	St. Paul, MN 55110
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-361-8041
FAX NUMBER:	651-351-8001
DATE OF SUBMISSION:	30 March 2009

1. **Identification of device**
   Proprietary Name: Insu*flow*® CO_2lonShield™
   Common Name: Gas Conditioner Device
   Classification Status: Class II per regulations 876.1500 Endoscope and Accessories
   Product Code: KOG (Endoscopy Accessory) and FCX (Insufflator for Endoscope)

2. **Equivalent devices**
   LEXION Medical believes that Insu*flow*® CO_2lonShield™ is substantially equivalent to the following devices:
   Insu*flow*®, K063546
   PROTOCO$_2$L Colon Insufflator, K030854
   Endoscopic CO_2 Regulator, K053008

   Insu*flow*® CO_2lonShield™ is the same gas conditioner accessory device as the Insu*flow*® cleared under 510(k) K063546 and has essentially the same intended use as the PROTOCO$_2$L and Endoscopic CO_2 Regulator predicate devices.

3. **Description of the Device**
   The Insu*flow*® CO_2lonShield™ device is a single use device that attaches to the outlet port of a regulated CO_2 source and is designed to warm and humidify the CO_2 gas stream prior to gas delivery during colonoscopy and intraoperative endoscopy procedures. The Insu*flow*® CO_2lonShield™ device consists of a disposable filter heater/humidifier tubing set and a control module that houses the control and safety circuits for the system.

   Regulated CO_2 gas flows into the Insu*flow*® CO_2lonShield™ device, through the in-line filter, continues along the tube to enter the Insu*flow*® CO_2lonShield™ device cassette that contains the heating element and humidification media, through a tube

that connects to an endoscope/colonoscope or rectal probe for gas delivery into the patient's gastroenterological cavity.

4. **Intended use**
Insu*flow*® CO_2lonShield™ is a gas conditioner accessory device for use during colonoscopy procedures, including CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy procedures, and intraoperative endoscopy procedures, intended to heat, humidify and filter a CO_2 gas stream for administration as a distention media.

5. **Technological characteristics, comparison to predicate device.**
Technically, the Insu*flow*® CO_2lonShield™ is identical to the Insu*flow*® cleared for market in 510(k) K063546 and essentially equivalent to the other predicates. The indications for use for the Insu*flow*® CO_2lonShield™ are patterned after the predicate devices.

6. **Discussion of performance testing.**
Extensive performance testing has been conducted to assure that the Insu*flow*® CO_2lonShield™ performs in accordance with its specifications and applicable standards. Details of that testing were provided in 510(k) K063546 and are summarized in Section 5.

7. **Conclusion**
Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that Insu*flow*® CO_2lonShield™ is substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2009

Mr. Bernard Horwath
Regulatory Consultant
LEXION Medical, LLC
5000 Township Parkway
ST PAUL MN 55110

Re: K090879
Trade/Device Name: Insuflow CO_2lonShield™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: July 20, 2009
Received: July 22, 2009

Dear Mr. Horwath:

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 (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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K090879

Device Name: Insu*flow*® CO_2lonShield™

Indications for Use:

Insu*flow*® CO_2lonShield™ is a gas conditioner accessory device for use during colonoscopy procedures, including CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy procedures, and intraoperative endoscopy procedures, intended to heat, humidify and filter a CO_2 gas stream for administration as a distention media.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090879