



Food and Drug Administration
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March 4, 2016

W.O.M World of Medicine Gmbh
Susanne Raab
Regulatory Consultant
1480 Cambridge Street
Cambridge, MA 02139

Re: K153513
Trade/Device Name: Insufflator 50L FM134
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF, OSV
Dated: November 25, 2015
Received: December 7, 2015

Dear Susanne Raab,

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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)

K153513

Device Name

Insufflator 50L FM134

Indications for Use (Describe)

The device Insufflator 50L FM134 is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1) General Information:

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Date Prepared: November 24, 2015

2) Proposed Device

Trade Name: Insufflator 50L FM134
Common Name: Carbon Dioxide Insufflator for Laparoscopy
and Vessel Harvesting
Classification Name: Insufflator, Laparoscopic
Regulation Number and Name: 21 CFR 884.1730, Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV

3) Predicate Devices:

Primary Predicate Device:

Trade Name: 45L Core Insufflator F114
510(k) Number: K063367
Classification Name: Insufflator, Laparoscopic
Regulation Number and Name: 21 CFR 884.1730, Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF



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Secondary Predicate Device:

Trade Name:	Nebulae™ I 50 LPM Insufflator
510(k) Number:	K120151
Classification Name:	Insufflator, Laparoscopic
Regulation Number and Name:	21 CFR 884.1730, Laparoscopic Insufflator
Regulatory Class:	II
Product Code:	HIF, FCX, OSV

4) Device Description:

The Insufflator 50L FM134 is a microprocessor controlled CO2 insufflator that consists of the following major components and features: a casing, a world power supply, pressure reducers, a venting system, redundant pressure measurement, a fluid sensor, a gas heater, a software controlled graphical user interface (GUI) touch screen and various setting keys and display elements. The Insufflator 50L FM134 is not intended to enter the sterile field, and cannot be sterilized. The device is to be used with specially designed single-use tube sets that are delivered sterile. Specifically, the proposed device is to be used with a single-use tube set with heating wire and integrated filter or with a single-use tube set with integrated filter but without heating wire.

5) Intended Use:

The device Insufflator 50L FM134 is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.



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6) Comparison of Technological Characteristics:

The Insufflator 50L FM134 is substantially equivalent to the 45L Core Insufflator F114 (K063367). Both the proposed device and the predicate device F114 have the same intended use and are used for the same indications. Specifically, the Insufflator 50L FM134 and the predicate device 45L Core Insufflator F114 are CO₂ insufflators intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. In addition, both the proposed device and the predicate device are designed with Standard, Pediatric and Bariatric operating modes that are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. Finally, both the proposed device and the predicate device incorporate a Vessel Harvesting operating mode that is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.

Furthermore, the Insufflator 50L FM134 and the predicate device 45L Core Insufflator F114 use the same basic operating principles and incorporate the same basic design. Both the proposed device Insufflator 50L FM134 and the predicate device 45L Core Insufflator F114 are microprocessor controlled CO₂ insufflators that consist of the same major components and incorporate the same features. In addition, both the proposed device and the predicate device 45L Core Insufflator F114 are to be used with specially designed sterile, single-use tube sets. The technical differences between the proposed device and the predicate device 45L Core Insufflator F114 consist of the following:

- The casing of the proposed device is slightly larger in dimensions and higher in weight.
- The maximum flow rate in the Bariatric operating mode has been



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increased from 45 l/min to 50 l/min.

- The proposed device does not incorporate an optional continuous pressure measurement feature.
- The proposed device is not equipped with an optional Sidne control system interface.
- The proposed device is not designed with a proprietary connection for the tube sets but instead incorporates an ISO 15/22 mm connector.
- The proposed device is designed with separate connections for gas insufflation and for gas heating.

The differences in the technological characteristics of both the proposed device Insufflator 50L FM134 and the predicate device F114 do not raise new questions of safety and effectiveness. Moreover, with regards to the increase of the maximum flow rate to 50 l/min, the Insufflator 50L FM134 is substantially equivalent to the predicate device Nebulae™ I 50 LPM Insufflator (K120151).

7) Performance Data:

Electrical safety and electromagnetic compatibility testing was performed by independent laboratories in accordance with the following standards:

- IEC 60601-1:2005 - Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; and
- IEC 60601-1-2:2007 – Medical Electrical Equipment – Part 1 -2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Test results demonstrate that the proposed device conforms to the above standards.

The software was developed, tested and verified in accordance with the FDA guidance document „*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*“ and in accordance with the following standard:



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- IEC 62304:2006 – Medical Device Software – Software Life Cycle Processes.

Design verification testing of the Insufflator 50L FM134 demonstrates that the device performs as intended and that the performance does not raise new questions of safety and effectiveness.

In addition, comparative bench testing was performed to demonstrate that the performance of the Insufflator 50L FM134 in the Bariatric operating mode is substantially equivalent to that of the predicate device 45L Core Insufflator F114. The comparative bench test included comparison of both devices with regards to reaching the set pressure, compensation of small and large leakages, overpressure scenarios and increase of the maximum flow rate from 45 l/min to 50 l/min. The test results demonstrate that the performance of the proposed device related to reaching the set pressure, compensation of small and large leakages and overpressure scenarios are comparable to the performance of the predicate device 45L Core Insufflator F114. In addition, the test results demonstrate that a maximum flow rate of 50 l/min leads on average to a slightly better insufflation performance of the proposed device compared to the predicate device 45L Core Insufflator.

Biocompatibility testing was performed on the insufflation tube sets of the proposed device Insufflator 50L FM134 in accordance with:

- ISO 10993-1:2009 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
- ISO 10993-5:2009 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization; and
- ISO 10993-11:2006 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.



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In addition, the insufflation tube set with heating wire of the proposed device FM134 was tested in accordance with ISO 10993 - 18:2005, Chemical characterization of materials.

ETO sterilization validation on the tube sets was performed in accordance with the below standards:

- ISO 11135-1:2007 – Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
- ISO 14937:2009 – Sterilization of health care products – General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices; and
- ISO 10993-7:2008 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
- AAMI TIR 28:2009, Product adoption and process equivalency for ethylene oxide sterilization

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 5 mg after 10 days of aeration (gas release) that remains on the tube set will not be exceeded. The sterility assurance level (SAL) was $\leq 10^{-6}$. Package and product integrity of the tube sets were tested in accordance with ISO 11607-1 – Packaging for terminally sterilized medical devices and ASTM-F-1980:2002 – Standard for accelerated aging of sterile medical device packages.

8) Conclusion:

Based on the same intended use, the same basic technological characteristics and performance testing, the Insufflator 50L FM134 is substantially equivalent to the predicate devices 45L Core Insufflator F114 and to the Nebulae™ I 50 LPM Insufflator. The differences between the proposed device and the predicate devices



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do not raise new questions of safety and effectiveness.