DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 23, 2017

Fisher & Paykel Healthcare
Nicole Senasac
Senior Regulatory Affairs Specialist
15 Maurice Paykel Place
East Tamaki, Auckland 2013
New Zealand

Re: K162582
Trade/Device Name: HumiGard™ Surgical Humidification System
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: May 16, 2017
Received: May 25, 2017

Dear Nicole Senasac:

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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162582

Device Name
HumiGard™ Surgical Humidification System

Indications for Use *(Describe)*
The HumiGard Surgical Humidification System is intended to warm and humidify carbon dioxide gas from an insufflator prior to entry into the surgical cavity during laparoscopic surgery.

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.

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510(k) Summary

Contact person/submitter	Nicole Senasac Senior Regulatory Affairs Specialist
Date prepared	8 May 2017
Contact details	15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Trade name	HumiGard™ Surgical Humidification System
Common name	Laparoscopic insufflator
Classification name	Insufflator, laparoscopic 21 CFR, 884.1730 Product Code HIF Class II
Predicate device	Lexion Medical Insuflow Device, Model 6198 (K063546) The predicate device has not been subject to a design related recall.

1.1. Device Description

The HumiGard™ Surgical Humidification System is designed to warm and humidify carbon dioxide (CO_2) gas after it leaves a commercially available insufflator (used to regulate the supply of CO_2 gas into the intended body cavity) and thereafter maintain the CO_2 gas in a warmed and humidified condition to the point of delivery into the patient's peritoneum via heated tubing.

The HumiGard™ Surgical Humidification System is comprised of a reusable Humidifier (SH870 Humidifier), supply voltage cord (115V or 230V) and the single use, sterile Humidified Insufflation Kit (ST520).

The ST520 Insufflation Kit is ETO sterilized (SAL 10^{-6}) and provides all of the necessary components needed to deliver the heated, humidified CO_2 gas during laparoscopic surgical procedures, including the insufflation tube, chamber, dry-line/filter assembly, funnel, and optional barb connector.

The SH870 Humidifier contains embedded software that controls the operation of the humidifier power and functions.

The HumiGard™ system conditions the CO_2 gas by using a water-filled chamber that is seated on a heater plate on the humidifier. Once the heater plate warms to the target temperature, the heated water in the chamber produces vapour that humidifies the gas as it passes through the chamber. The surgical humidifier also provides power to the heating element (i.e., the heaterwire) within the heated insufflation tube to maintain the desired heat and humidity of the CO_2 gas as it travels from the chamber to the patient interface (trocar/cannula).

1.2. Intended Use

The HumiGard™ Surgical Humidification System is intended to warm and humidify carbon dioxide gas from an insufflator prior to entry into the surgical cavity during laparoscopic surgery.

Table 1-2

Indications for use and intended use			
Indications for use	The HumiGard™ Surgical Humidification System is intended to warm and humidify carbon dioxide gas from an insufflator prior to entry into the surgical cavity during laparoscopic surgery.	The Lexion Medical Insufiow® device is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.	***Identical -*** *humidification of CO_2 gas used in laparoscopic surgical procedures*
Intended use	The HumiGard™ Surgical Humidification System is intended to warm and humidify carbon dioxide gas from an insufflator prior to entry into the surgical cavity during laparoscopic surgery.	The Lexion Medical Insufiow® device is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.	***Identical -*** *humidification of CO_2 gas used in laparoscopic surgical procedures*

1.3. Device Materials

A summary of the patient contact materials contained in ST520 insufflation kit is provided below in **Table 1-2**.

	Component	**Material type**	**Nature of Body Contact**	
			Contact	**Duration**
1	Elbow insufflation No port	HDPE	Tissue/ Bone/ Dentin	Limited
2	Heaterwire socket	HDPE	Tissue/ Bone/ Dentin	Limited
3	Heaterwire (Insulation)	HDPE	Tissue/ Bone/ Dentin	Limited
4	Luer connector boss	HDPE	Skin	Limited
5	Luer connector male	Polycarbonate	Tissue/ Bone/ Dentin	Limited
6	Luer connector lock ring	Polycarbonate	Skin	Limited
7	Tube inner smooth insufflation	Polyolefin Elastomer	Tissue/ Bone/ Dentin	Limited
8	Tube outer insufflation	LDPE	Skin	Limited
9	Band Insufflation tube	Tyvek/ Nylon film	No contact	Not applicable
10	HEPA Filter	PP	Tissue/ Bone/ Dentin	Limited
11	15Male – 8mm connector	Styrene-Butadene Copolymer	Tissue/ Bone/ Dentin	Limited

Component		Material type	Nature of Body Contact	
			Contact	Duration
12	1m PVC Tubing	PVC	Tissue/ Bone/ Dentin	Limited
13	22Female – 8mm connector	Styrene-Butadene Copolymer	Tissue/ Bone/ Dentin	Limited
-	Glue (Note 2)	Medical device adhesive	Tissue/ Bone/ Dentin	Limited
14	Chamber Moulded	Blend of K-resin & PS	Tissue/ Bone/ Dentin	Limited
15	Gasket Santoprne 200Ser BseMk2	TPE	Tissue/ Bone/ Dentin	Limited
16	Base Sft Anodised MR200 Series	Aluminium	Tissue/ Bone/ Dentin	Limited
17	Printing	Ink	No contact	Not applicable
18	Adaptor 22M/15F Barb Surgical	Blend of K-resin & Styron	Tissue/ Bone/ Dentin	Limited
19	Tube Silicon 4.8mm dia	Silicon	Tissue/ Bone/ Dentin	Limited
20	Funnel	PP	Tissue/ Bone/ Dentin	Limited

1.4. Technological Characteristics Comparison

The primary differences between the HumiGard™ system and predicate Insuflow device are the point at which the water is humidified and the method used to humidify the CO_2 gas.

The HumiGard™ system humidifies the CO2 gas proximal to the gas source, while the gas is humidified proximal to the patient with the Insuflow device.

The HumiGard™ system conditions the gas from the control unit by using a water-filled chamber that is seated on a heating plate. Once the heater plate warms to the target temperature, the heated water in the chamber produces vapour that humidifies the CO_2 gas as it passes through the chamber. The Insuflow laparoscopic gas conditioning device provides humidification directly within the disposable filter heater/humidifier tubing set. The tubing set includes a heating mechanism, a small water chamber, and a “wick” of moistened material through which the heated CO_2 gas passes and is thus humidified.

Technical Specifications			
Design / technological characteristic for comparison	**Subject device (HumiGard™ Surgical Humidification System)**	**Predicate device (Insuflow Device, Model 6198)**	**Comments**
Chamber capacity	180 mL	10 mL	Capacity does not introduce any different questions of safety or effectiveness as the capacity is commensurate with the size of the respective water chambers.
Humidification Element Position	Proximal to the gas source	Proximal to the patient	The humidification element position does not introduce any different questions of safety or effectiveness as it has no impact on the humidity output performance. HumiGard and Insuflow provide equivalent relative humidity and output temperature.
Humidity Performance	At 32.1 ºC	At 32.4 ºC	**Difference is not clinically significant**
Maximum Input Flow Rate	≤ 45 L/min	40 L/min	**Equivalent**
Achieved Flow Rate	15 L/min	7-8 L/min	Achieved flow rate does not introduce any different questions of safety or effectiveness as both devices are capable of operation within the flow parameters of commercially available insufflators

1.5. Non-Clinical Performance Data

Testing for the HumiGard™ system was conducted in accordance with the following standards:

Standard	Title
IEC 60601-1:2005 + A1:2012 (Ed 3.1)	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
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
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-10: 2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-5:2009/(R) 2014	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ANSI/AAMI/ISO 11607-1: 2006	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems

ANSI/AAMI/ISO 11607-2: 2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-2:2009	Sterilisation of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilisation process
ISO 11135:2014	Sterilization of health care products—Ethylene Oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices

Test results demonstrate that the HumiGard™ system conforms to the above-referenced standards.

Biocompatibility evaluation of cytotoxicity, irritation and sensitization for the ST520 kit was conducted in accordance with FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" (June 2016). The results of the biocompatibility testing were acceptable.

The HumiGard™ system software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since it a failure of the device software could result in minor injury prior to mitigation of hazards, either to a patient or to a user of the device. The software validation documentation provided was complete and acceptable.

Performance verification testing of the HumiGard™ system consisted of temperature output, humidity output, flow rate, leak rate, compliance, maximum delivered enthalpy, surface temperature of the tubing, condensation, and outlet connection strength. The verification testing demonstrated that the device performs as intended and met appropriate acceptance criteria.

The results of the comparative bench testing demonstrate that the performance of the HumiGard™ system with respect to these key performance characteristics are comparable to the predicate Insuflow device.

1.6. Clinical Performance Data

Substantial equivalence was did not include an assessment of clinical performance data.

1.7. Conclusions

Based on the same intended use, different technological characteristics that do not raise different questions of safety and effectiveness and acceptable performance testing, the HumiGard™ Surgical Humidification System is as safe, as effective, and performs as well as the predicate Insuflow device.