DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 19, 2017

Teleflex Medical, Inc.
Brian Gall
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K162242
Trade/Device Name: Comfort Flo Humidification System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: December 16, 2016
Received: December 19, 2016

Dear Mr. Gall:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental 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)*
K162242

Device Name
Comfort Flo Humidification System

Indications for Use *(Describe)*
The Comfort Flo Humidification System provides a continuous flow of heated and humidified gas to spontaneously breathing patients. It is indicated for single use by neonate/infant, pediatric, and adult patients in professional healthcare environments.

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

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-228-4350
Fax: 919-361-3939

B. Contact Person

Brian Gall
Senior Regulatory Affairs Specialist

C. Date Prepared

16 December 2016

D. Device Name

Trade Name:	Comfort Flo Humidification System
Classification Name:	Respiratory Gas Humidifier
Product Code:	BTT
Regulation Number:	868.5450
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to the following predicate devices:

- Comfort Flo Humidification System – K131912

F. Device Description

The Comfort Flo Humidification System is intended to deliver heated and humidified respiratory gases to spontaneously breathing patients. The Comfort Flo Humidification System is designed to be used in conjunction with the Neptune Heated Humidifier with ConchaSmart Technology for neonate/infant, pediatric, and adult populations. The Comfort Flo Humidification System includes a Heated Wire Breathing Circuit, a ConchaSmart Column, and various Class I exempt accessories.

G. Indications for Use

The Comfort Flo Humidification System provides a continuous flow of heated and humidified gas to spontaneously breathing patients. It is indicated for single use by neonate/infant, pediatric, and adult patients in professional healthcare environments.

H. Technological Characteristics Comparison to the predicate

Comparative Characteristics	Comfort Flo Humidification System K131912	Proposed Comfort Flo Humidification System
Intended Use/Indications for Use	To provide a continuous flow of heated and humidified gas to spontaneously breathing patients.	The Comfort Flo Humidification System provides a continuous flow of heated and humidified gas to spontaneously breathing patients. It is indicated for single use by neonate/infant, pediatric, and adult patients in professional healthcare environments.
Environment of Use	Professional healthcare environment (ex. Hospital)	Professional healthcare environment (ex. Hospital)
Patient Population	Neonate/infant, pediatric, Adult	Neonate/infant, pediatric, Adult
Gas Source Compatibility	Non-Ventilator (continuous flow system)	Non-Ventilator (continuous flow system)
Compatible Humidifiers	ConchaTherm Neptune Heated Humidifier	ConchaTherm Neptune Heated Humidifier
Compatible Columns	ConchaSmart Column	ConchaSmart Column
Humidification Method	Paper wick within the sterile Concha Column. Water fills the bottom of the column and is absorbed up the wick which is directly in the air flow. The column is warmed to increase water and air temperature to aid the creation and absorption of water vapor into the airstream.	Paper wick within the sterile Concha Column. Water fills the bottom of the column and is absorbed up the wick which is directly in the air flow. The column is warmed to increase water and air temperature to aid the creation and absorption of water vapor into the airstream.
Gas Delivery	Inspiratory limb only	Inspiratory limb only
Water Type	Sterile water sold separately	Sterile water sold separately
Enthalpy	Per ISO 8185:2007 Thermal overshoot to the patient connection port limited to an energy equivalent to 43°C and 100% relative humidity when averaged over any 30 second period	Per ISO 8185:2007 Thermal overshoot to the patient connection port limited to an energy equivalent to 43°C and 100% relative humidity when averaged over any 30 second period
Disposable vs. Reusable	Disposable, single use	Disposable, single use
Sterility	Gamma sterilized ConchaSmart column. Circuit and all other accessories are non-sterile	Non-sterile
Patient Interface Type	Nasal Cannula (sold separately, not part of this 510(k))	Nasal Cannula (sold separately, not part of this 510(k))
Comfort Flo Humidification System Components	• Heated Wire Breathing Circuit • ConchaSmart Column • Various Class 1 Exempt devices	• Heated Wire Breathing Circuit • ConchaSmart Column • Various Class 1 Exempt devices

Comparative Characteristics	Comfort Flo Humidification System K131912	Proposed Comfort Flo Humidification System
Heated Wire Breathing Circuit Tubing	10 mm ID smooth bore PVC tubing (catalog# 2010 and 2414) 15 mm ID corrugated Polypropylene/Engage tubing (catalog# 2415 and 2416)	10 mm ID smooth bore PVC tubing (catalog# 2010 and 2414) 15 mm ID corrugated Polypropylene/Engage tubing (catalog# 2415 and 2416)
Simulated Use	Circuit, column, and nasal cannula assembly operate at 37°C (+/- 2°C) for up to 37 days with visible condensation, without loss of functional integrity.	Circuit, column, and nasal cannula assembly operate at 37°C (+/- 2°C) for up to 21 days with visible condensation, without loss of functional integrity.
Humidity Output	System delivers gas conditioned at or near 37°C and 10mg/l of humidity to the patient interface from 1 to 60 LPM.	System delivers gas conditioned at or near 37°C and 10mg/l of humidity to the patient interface from 1 to 60 LPM.
Condensation (rainout)	System controls amount of condensation in the circuit using the heated wire settings of the ConchaTherm Neptune Heated Humidifier from 1 to 60 LPM.	System controls amount of condensation in the circuit using the heated wire settings of the ConchaTherm Neptune Heated Humidifier from 1 to 60 LPM.
Shelf Life	5 year shelf life on the Corrugated Comfort Flo Kits (catalog# 2415 and 2416)	1 year shelf life on the Corrugated Comfort Flo Kits (catalog# 2415 and 2416)
Useful Life	30 Days	21 Days
Breathing Circuit Materials	Polypropylene	Polypropylene (different blend)
	PVC	PVC
	Polypropylene	Polypropylene
	Polystyrene	Polystyrene
	Silicone	Silicone
	Cyclohexanone	Cyclohexanone
	Engage	Engage (different blend)
	Cyclohexane / Styrene Butadiene (adhesive)	Cyclohexane / Styrene Butadiene (adhesive)

The following are the primary differences in the proposed Comfort Flo Humidification System:

- The Indications for Use Statement has been updated per to better align with 21 CFR 814.20(b)(3)(i). There are no changes to the content or meaning of the Indications for Use from the predicate to the proposed device.
- The ConchaSmart column (part of the Comfort Flo Humidification System) included in the predicate device was sterilized by gamma radiation. The circuit and other accessories were non-sterile. The ConchaSmart column was made non-sterile in submission K141940. The proposed Comfort Flo Humidification system is completely non-sterile.

- The shelf life and useful life of the predicate are different from the proposed device. The proposed shelf life and useful life are based on test data.
- There are two new materials in the proposed Heated Wire Breathing Circuit. The circuit has undergone all necessary biocompatibility and performance tests

I. Performance Data

The following testing was performed on the proposed device.

- ISO 8185:2007 – Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems, applicable sections ISO 5356-1:2004 – Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets, applicable sections
- ISO 5367:2000 (Section 4.4, and Annexes D and E, per ISO 8185) – Breathing tubes intended for use with anaesthetic apparatus and ventilators, applicable sections
- Biocompatibility
    - ISO 10993-1:2009 – Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
    - 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
    - ISO 10993-12:2012 – Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
    - ISO 10993-17:2002 – Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances
    - ISO 10993-18:2002 – Biological evaluation of medical devices -- Part 18: Chemical characterization of materials
- Shelf life
- Useful life

J. Summary of Non-Clinical Testing

Test Description	Test Objective	Results
Shelf life / Useful life testing	The proposed Corrugated Comfort Flo Heated Wire Breathing Circuit, when used with the Hudson RCI Neptune Heated Humidifier must perform as intended when subject to the following test methods: • Pre- and Post-aging Visual Inspection • Length per ISO 5367 • Connection strength testing • Maximum Temperature / Minimum flow testing • ISO 8185 Section 101 • Useful life testing • Rainout control	PASS

Test Description	Test Objective	Results
Enthalpy related to flow variations, Resistance to Flow, Resistance to Flow with a bend, and Leakage, Humidity Output, Enthalpy related to use and system errors, Warm Up Time and Temperature Tracking	The proposed Corrugated Comfort Flo Heated Wire Breathing Circuit, when used with the Hudson RCI Neptune Heated Humidifier must perform as intended post accelerated aging and useful life testing when subject to the test methods from the following applicable sections of ISO 8185: • Section 51.103 • Section 56.101.2 and 56.101.3 • Section 101 • Section 51.103 with faults from 3.6 bb • Section 6.8.2 a) 14 • Section 50.2 cc	PASS

K. Conclusion

The proposed Comfort Flo Humidification System is substantially equivalent to the predicate devices listed above in that the indications for use, the intended use, and fundamental scientific technology remain unchanged. The difference between the predicate device and the proposed device is the material of construction of the corrugated tubing on the Comfort Flo Heated Wire Breathing Circuit. The tubing material is being changed to a different grade of the same material. The proposed device was tested with equivalent biocompatibility and performance testing as the predicate, and met all of the acceptance criteria.

The device data and test results demonstrate that the device is substantially equivalent to the predicate device.