K131912

MAR - 6 2014

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8050
Fax: 919-433-4996

B. Contact Person

Amanda Webb
Regulatory Affairs Specialist

C. Date Prepared

February 5, 2013

D. Device Name

Trade Name:	ConchaTherm Neptune Heated Humidifier
Common Name:	Respiratory Gas Humidifier
Product Code:	BTT
Regulation Number:	868.5450
Classification:	II
Classification Panel:	Anesthesiology

Trade Name:	ConchaSmart Column
Common Name:	Respiratory Gas Humidifier
Product Code:	BTT
Regulation Number:	868.5450
Classification:	II
Classification Panel:	Anesthesiology

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:

- ConchaTherm Neptune Heated Humidifier – K063758
- Minimal Compliance Column – K993355
- Comfort Flo Humidification System – K061736

F. Device Description

The ConchaTherm Neptune Heated Humidifier is an active heated humidifier designed to provide heat and moisture to the medical gases delivered to a patient through continuous flow, invasive ventilation or non-invasive ventilation.

The ConchaSmart Column is an accessory to the ConchaTherm Neptune Heated Humidifier. It is a single use, disposable humidifier cartridge which is intended for neonatal, infant, pediatric, and adult patients requiring heated humidification. The ConchaSmart Column is used by inserting the column into the center of the ConchaTherm Neptune.

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 ConchaTherm Neptune Heated Humidifier 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

ConchaTherm Neptune Heated Humidifier:
The ConchaTherm® Neptune TM is a respiratory humidifier designed to heat and humidify respiratory gases delivered via endotracheal tubes, nasal cannula or face masks to adult, pediatric, infant and neonatal patients. This system may be used with either conventional (non-heated wire) breathing circuits or compatible (21-volt) Hudson Respiratory Care Incorporated (RCI) heated-wire circuits.

The ConchaTherm® NeptuneTM can be used with ventilators, continuous flow systems, oxygen diluters and blenders, adjustable nebulizer adapters for aerosol therapy, or non-flammable anesthesia gases to help maintain patient body temperature.

ConchaSmart Column:
When used with the Hudson RCI ConchaTherm Neptune Heated Humidifier and Hudson RCI ventilator circuits, the ConchaSmart Column provides heated humidification for patients with and without an artificial airway in place.

Comfort Flo Humidification System:
To provide a continuous flow of heated and humidified gas to spontaneously breathing patients.

H. Technological Characteristics Comparison to the predicate

The proposed ConchaTherm Neptune Heated Humidifier, ConchaSmart Column and Comfort Flo Humidification System are substantially equivalent to the predicate devices listed above in that the indications for use, the intended use, and fundamental scientific technology remain unchanged. The following tables summarize the technological differences between the proposed and predicate devices.

ConchaTherm Neptune

Different Technological Characteristic	Predicate Device
Ability to side mount the unit	Only allowed for rear mounting the unit
Heated Wire Subglottic: 32° - 40°C (Intubated Mode)	Heated Wire Subglottic: 32° - 39°C (Intubated Mode)
Supraglottic (Non-Invasive): 28° - 37°C	Supraglottic (Non-Invasive): 30° - 37°C
Continuous Flow Applications 1-60LPM	Continuous Flow Applications 1-40LPM
Compliant with ISO 8185:2007	Compliant with ISO 8185:1997
Low Water Notification	Does not have a low water notification
Auto Settings Mode – allows clinician to set default settings	Does not allow clinician to set default settings

ConchaSmart Column

Different Technological Characteristic	Predicate Device
Includes ability to trigger low water notification in the ConchaTherm Neptune	Does not interact with humidifier to provide a low water notification
Labeled for 30 day Useful Life	Not labeled for useful life

Comfort Flo Humidification System

Different Technological Characteristic	Predicate Device
Includes above ConchaSmart Column	Included the Comfort Flo Column
Additional product offering with a corrugated heated wire breathing circuit	Only included a smooth bore PVC heated wire breathing circuit
Shelf Life on corrugated Comfort Flo Humidification System	Does not include a shelf life on full Comfort Flo Humidification System
Rated flow for adults is 1-60 LPM	Rated flow for adults is 1-40LPM
Labeled for 30 day Useful Life	Tested but not labeled for useful life

I. Performance Data

The following testing was performed on the proposed devices.

- ISO 8185
- IEC 60601-1
- IEC 60601-1-8
- IEC 60601-1-4
- Biocompatibility
    - ISO 10993-3
    - ISO 10993-5

  - ISO 10993-6
  - ISO 10993-10
- Sterility
  - ISO 11137-1
  - ISO 11137-2
- Shelf life
- Useful life
- Software Verification and Validation

J. Conclusion

The device data and test results demonstrate that the device is as safe and as effective as the predicate device and therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 6, 2014

Teleflex Medical Incorporated
Ms. Amanda Webb
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K131912
Trade/Device Name: ConchaTherm Neptune Heated Humidifier
ConchaSmart Column
Comfort Flo Humidification System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: February 10, 2014
Received: February 11, 2014

Dear Ms. Webb:

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.

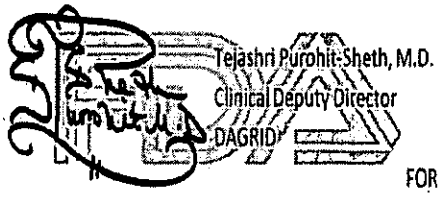
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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. 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/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,



FOR

Erin I. Keith, M.S.
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)*
K131912

Device Name
Comfort Flo Humidification System

Indications for Use *(Describe)*
To provide a continuous flow of heated and humidified gas to spontaneously breathing patients.

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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K131912

Device Name
ConchaSmart Column

Indications for Use *(Describe)*
When used with the Hudson RCI ConchaTherm Neptune Heated Humidifier and Hudson RCI ventilator circuits, the ConchaSmart Column provides heated humidification for patients with and without an artificial airway in place.

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)

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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)*
K131912

Device Name
ConchaTherm Neptune Heated Humidifier

Indications for Use *(Describe)*
The ConchaTherm® Neptune® is a respiratory humidifier designed to heat and humidify respiratory gases delivered via endotracheal tubes, nasal cannula or face masks to adult, pediatric, infant and neonatal patients. This system may be used with either conventional (non-heated wire) breathing circuits or compatible (21-volt) Hudson Respiratory Care Incorporated (RCI) heated-wire circuits.

The ConchaTherm® Neptune® can be used with ventilators, continuous flow systems, oxygen diluters and blenders, adjustable nebulizer adapters for aerosol therapy, or non-flammable anesthesia gases to help maintain patient body temperature.

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)

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