August 2, 2018

Teleflex Medical, Inc
Brian Gall
Senior Regulatory Affairs Specialist, Respiratory Division
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K173280
Trade/Device Name: Neonatal ConchaSmart Breathing Circuits
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: June 29, 2018
Received: July 2, 2018

Dear Brian 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173280

Device Name
Neonatal ConchaSmart Breathing Circuit

Indications for Use *(Describe)*
The Neonatal ConchaSmart Breathing Circuits are intended for neonatal and infant patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator or Infant Flow Generator (for single limb configuration) and include heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier. The heated wires are intended to aid in maintaining the set patient temperature and minimize condensation in the ventilator tubing.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 919-228-4350

B. Contact Person

Brian Gall
Regulatory Affairs Group Lead, Respiratory Division

C. Date Prepared

31 July 2018

D. Device Name

Trade Name:	Neonatal ConchaSmart Breathing Circuits
Common Name:	Breathing system heater
Product Code:	BZE
Regulation Number:	868.5270
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

The Neonatal ConchaSmart Breathing Circuits are substantially equivalent to the following devices:

- K103767 - RT265 and RT266 Dual Heated Infant Breathing Circuits

In addition, the following devices are used as reference devices as described:

K140556 has been added as a reference 510(k). The primary reason for referencing K140556 is that this is the adult version of the proposed device. The adult breathing circuits were added as a reference for the following primary reasons:

- Different technological characteristics (single vs. dual limb) do not raise different questions of safety and effectiveness from the predicate device since the adult circuit is available in both configurations.
- The materials used in the proposed neonatal breathing circuit and the reference are similar and well understood.
- The useful life testing strategy of the reference device was accepted. It is an equivalent test method to the proposed device.
- The heated wires used in the reference device are similar to the proposed device. The intent of using the adult circuits as a reference was to show that Teleflex has market knowledge of the interaction of this type of heated wire being used with similar materials with the Hudson RCI Neptune Heated Humidifier system.

K151959 has been added as a reference 510(k). The primary reason for referencing K151959 the following:

- It is a single limb breathing circuit cleared to be used with a heated humidifier for neonatal and infant patient populations.
- The testing related to the single limb configuration was similar (biocompatibility to ISO 10993; circuit construction and performance to ISO 5356-1, ISO 5367, and ISO 8185; and electrical testing to IEC 60601-1).

F. Device Description

The Neonatal ConchaSmart Breathing Circuits are intended for neonatal and infant patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator or Infant Flow Generator (for single limb configuration) and includes heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier. The heated wires are intended to aid in maintaining the set patient temperature and minimize condensation in the ventilator tubing.

These devices are made of corrugated tubing (10mm in diameter), which houses the heated wires and are kitted with various adaptors and connectors to aid the respiratory care clinician in system configuration. In general these heated wire circuits are connected to both a ventilator and a Hudson RCI Neptune Heated Humidifier. The single limb configuration is compatible with the CareFusion Infant Flow system.

All Neonatal ConchaSmart Breathing Circuits have a useful life of 21 days. Neonatal ConchaSmart Breathing Circuits are sold non-sterile.

G. Indications for Use

The Neonatal ConchaSmart Breathing Circuits are intended for neonatal and infant patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator or Infant Flow Generator (for single limb configuration) and include heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier. The heated wires are intended to aid in maintaining the set patient temperature and minimize condensation in the ventilator tubing.

H. Technological Characteristics - Comparison to the Predicate

The proposed Heated Wire Breathing Circuits are substantially equivalent to the predicate device as the intended use, fundamental scientific technology, and operating principles are the same. The circuits differ with regards to limb configurations, tubing dimensions, and materials, however through testing and the introduction of reference predicates, the proposed devices are substantially equivalent to the predicate as indicated below:

Comparative Characteristics	RT265 and RT266 Dual Heated Infant Breathing Circuits **Predicate (K103767)**	Neonatal ConchaSmart Breathing Circuits **Proposed**
Indications for Use	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4LPM, and the RT266 is for flow rates between 0.3LPM and 4LPM.	The Neonatal ConchaSmart Breathing Circuits are intended for neonatal and infant patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator or Infant Flow Generator (for single limb configuration) and include heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier. The heated wires are intended to aid in maintaining the set patient temperature and minimize condensation in the ventilator tubing.
Intended Use	The RT265 and RT266 infant breathing circuits are intended to deliver humidified breathing gases for administration to an infant patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed. Thus humidified gases via heated breathing circuit may be indicated for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. These gases may be delivered by facemask or through bypassing upper airways, for example use of an endotracheal tube.	The proposed Neonatal ConchaSmart breathing circuits are intended to deliver humidified breathing gases for administration to an infant/neonate patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed. Thus humidified gases via heated breathing circuit may be indicated for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. These gases may be delivered by nasal prongs using the CareFusion Infant Flow system and the single limb circuit, or through bypassing upper airways, for example through the use of an endotracheal tube with the dual limb configuration.
Environment of Use	Professional Healthcare Environment	Professional Healthcare Environment
Patient Population	Infant	Neonate/Infant
Compatible Humidifiers	MR850 Heated Humidifier	Hudson RCI Neptune Heated Humidifier

Comparative Characteristics	RT265 and RT266 Dual Heated Infant Breathing Circuits **Predicate (K103767)**	Neonatal ConchaSmart Breathing Circuits **Proposed**
Circuit Configurations	Dual Limb Heated Wire Circuit	Dual Limb Heated Wire Circuit Single Limb Heated Wire Circuit
Flow Range	RT265 – flow rates greater than 4LPM RT266 – 0.3LPM and 4LPM"	1-15 LPM
Kit components	Remote temperature port tubing Water feed tube Tubing adaptor set 15 mm adaptors Luer tee connector Step down adaptor Humidifier limb	ConchaSmart Column, Non-sterile Airway adaptors and connectors Humidifier Limb tubing with connectors Remote Temp Port tubing with connectors Pressure Line tubing with connectors
Disposable vs. Reusable	Disposable	Disposable
Circuit Tubing Diameter	11mm	10mm
Design	Corrugated	Corrugated
Wire Maximum Power	Unknown	Single Limb: 21 Watts Dual Limb: 21 to 30 Watts
Min Circuit Resistance	Unknown	Single Limb: 3 Ohms Dual Limb: 0.8 to 4.7 Ohms
Wire Material	Unknown	Single Limb: Nickel Chromium Iron Dual Limb: Nickel Chromium Iron and Nickel Chromium
Wire Length	Unknown	Single Limb: 116 inches Dual Limb: 94 to 141 inches
Heated Wire Specification	Unknown	Maximum of 2.5W per linear foot
Circuit Length	1.5 meters	Single Limb: 1.8 meters Dual Limib: 1.5 meters to 1.8 meters
Resistance to Flow (inspiratory limb)	2 cmH_2O @ 13LPM	Less than 1.89 cmH_2O @ 2.5LPM (per ISO 5367:2014)
Resistance to Flow (expiratory limb)	2 cmH_2O @ 13LPM	Less than 1.89 cmH_2O @ 2.5LPM (per ISO 5367:2014)
Compliance	0.81 ml/cmH_2O	Less than 1.5 ml/cmH_2O @ 60 cmH_2O (per ISO 5367:2014)
Leakage	Maximum Circuit Gas Leakage: 75ml/min @ 60 cmH_2O	Less than 30 ml/min @ 60 cmH_2O (per ISO 5367:2014)
Useful Life	7 days	21 days

Comparative Characteristics	RT265 and RT266 Dual Heated Infant Breathing Circuits **Predicate (K103767)**	Neonatal ConchaSmart Breathing Circuits **Proposed**
Standards	Interface Connection: ISO 5356-1 (no other standards cited in 510(k) summary or on labeling)	Interface Connection: ISO 5356-1:2015 Compliant to ISO 5367:2014
Heated Wire Breathing Circuit Materials	Not disclosed in 510(k) Summary	Tested per ISO 10993 and Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Similarities

The proposed device and predicate are similar in that they have the same intended use and same indications for use. They are used for the same patient population in the dual limb configuration and were subjected to and passed testing to the same performance (ISO 5367, ISO 8185, ISO 5356-1), biological (ISO 10993), and electrical (IEC 60601-1 and IEC 60601-1-2) standards.

Differences

The main differences are the limb configuration of single limb, the flow rates, and the use of the device with the Neptune Heated Humidifier. With respect to the limb configurations, a reference predicate was introduced that is a single limb configuration cleared for the neonatal / infant population for use with a heated humidifier. The physical and electrical characteristics of the proposed device were testing according to IEC 60601-1 and IEC 60601-1-2 and were appropriate for the indicated Heated Humidifier (Hudson RCI Neptune). For the tubing dimensions, testing to ISO 5367 showed that the proposed device and the predicate were substantially equivalent.

I. Performance Data

The following testing was performed on the proposed devices.

- IEC 60601-1 – Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995, applicable sections
- ISO 8185:2007 – Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems, applicable sections
- ISO 5356-1:2015 – Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets, applicable sections
- ISO 5367:2014 – Anaesthetic and respiratory equipment -- Breathing sets and connectors, 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 10993-17:2002 – 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 (accelerated aging)
- Useful life

The proposed devices were tested to the neonatal requirements of ISO 5367:2014. In addition, testing was performed to ensure compatibility with the Hudson RCI Neptune Heated Humidifier and a useful life of 21 days. Cytotoxicity, sensitization, irritation, and Extractable and Leachable testing were performed to demonstrate biocompatibility of the patient contacting materials.

J. Summary on Non-Clinical Testing

Test Description	Test Objective	Results
Shelf Life testing	The proposed Neonatal ConchaSmart Breathing Circuits were aged according to *ASTM F1980: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* for the equivalent of one year.	N/A (for test setup only)
Useful Life testing	The proposed Neonatal ConchaSmart Breathing Circuits were tested for a 21 day useful life after accelerated aging equivalent to one year using worst case use scenarios. During and after the useful life testing, the circuits were tested for applicable sections of ISO 5367	PASS
All testing below was conducted on the proposed devices after the one year accelerated shelf life and 21 day useful life testing. This was considered the worst case.		
Design Verification testing: ISO 8185:2007 Testing	The proposed Neonatal ConchaSmart 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 applicable sections of *ISO 8185:2007 Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems*	PASS
Design Verification testing: IEC 60601-1:1988 + A1:1991 + A2:1995 Testing	The proposed Neonatal ConchaSmart 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 applicable sections of *IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety*:	PASS

Test Description	Test Objective	Results
Design Verification testing: ISO 5367:2014 Testing	The proposed Neonatal ConchaSmart 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 applicable sections of *ISO 5367:2014 – Anaesthetic and respiratory equipment -- Breathing sets and connectors*	PASS
Design Verification testing: ISO 5356-1:2015 Testing	The proposed Neonatal ConchaSmart Breathing Circuit must perform as intended post accelerated aging and useful life testing when subject to the test methods from the following applicable sections of *ISO 5356-1:2015 – Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets*:	PASS
Design Verification testing: Additional Design Testing	The proposed Neonatal ConchaSmart Breathing Circuit must perform as intended post accelerated aging and useful life testing when subject to the test methods from additional design testing including component break and slip testing.	PASS

K. Conclusion

As with the predicate, all of the acceptance criteria required through the use of the harmonized standards (including performance, biocompatibility, and electrical as discussed above) were met for the proposed device. In addition, the circuit was found to function as intended when used with the Neptune Heated Humidifier, for which it is intended to use. The device data and test results demonstrate that the devices meet the applicable standards for breathing circuits and are substantially equivalent to the predicate device.