DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 24, 2014

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

Re: K140556
Trade/Device Name: ConchaSmart and ISO-GARD Breathing Circuits
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 27, 2014
Received: August 28, 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 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" (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 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**

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Device
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)*
K140556

Device Name
ConchaSmart and ISO-GARD Breathing Circuit

Indications for Use *(Describe)*
The ConchaSmart and ISO-GARD Breathing Circuits are intended for adult patients in professional healthcare facilities as a conduit for respiratory gas between a patient and a ventilator 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 breathing circuit.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

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

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

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

### B. Contact Person

Amanda Webb
Senior Regulatory Affairs Specialist

### C. Date Prepared

September 24, 2014

### D. Device Name

| | |
|---|---|
| Trade Name: | ConchaSmart and ISO-GARD Breathing Circuits |
| Common 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 device:

- Hudson RCI Heated Wire Circuit – K031383

### F. Device Description

ConchaSmart and ISO-GARD breathing circuits provide a conduit for respiratory gases between the patient and the ventilator/Hudson RCI Neptune Heated Humidifier. The heated wires inside the breathing circuits are used to minimize condensation in the circuit and to aid in maintaining the designated humidity and temperature of the respiratory gas. ConchaSmart and ISO-GARD breathing circuits are intended for use with adult patient populations in professional healthcare environments.

These devices are made of corrugated tubing (22 mm in diameter) which house the heated wires and are kitted with various adaptors and connectors to aid the respiratory care clinician in system configuration.

## G. Indications for Use

The ConchaSmart and ISO-GARD Breathing Circuits are intended for adult patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator 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.

## H. Technological Characteristics Comparison to the predicate

The proposed Heated Wire Breathing Circuits are substantially equivalent to the predicate devices listed above in that the intended use and fundamental scientific technology remain unchanged. The following table summarizes the technological differences between the proposed and predicate devices.

| Comparative Characteristics | Hudson Heated Wire Breathing Circuits (K031383) | Proposed ISO-GARD and ConchaSmart breathing circuits |
|---|---|---|
| Indications for Use | The Hudson Heated Wire Ventilator Circuit is intended as a conduit for respiratory gas between a patient and a ventilator, and includes heated wires for use with a Concha Column Humidifier; the heated wires are intended to minimize condensation in the ventilator tubing. | The ConchaSmart breathing circuit is intended as a conduit for respiratory gas between a patient and a ventilator 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 breathing circuit. |
| Intended Use | Act as a conduit for gas delivery to a patient. | Same |
| Environment of Use | Professional Healthcare Environments | Same |
| Patient Population | Adult | Same |
| Compatible Humidifiers | All Hudson ConchaTherm Heated Humidifiers | Hudson RCI Neptune Heated Humidifier |
| Disposable vs. Reusable | Disposable | Same |
| Simulated Use | Not labeled for useful life | Labeled for 30 day useful life |

| Comparative Characteristics | Hudson Heated Wire Breathing Circuits (K031383) | Proposed ISO-GARD and ConchaSmart breathing circuits |
|---|---|---|
| Standards | Tested to some sections of ISO 5367 | Compliant to ISO 5367 and ISO 5356-1 |
| Wye Material | Polypropylene | Clearblend |
| Tubing Material | Polyethylene/EVA | Polypropylene/Engage |

## I. Performance Data

The proposed devices were tested to ensure compliance to ISO 5367 (Breathing tubes intended for use with anaesthetic apparatus and ventilators) and ISO 5356-1 (Anesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets). In addition, testing was performed to ensure compatibility with the Hudson RCI Neptune Heated Humidifier and a useful life of 30 days. Cytotoxicity, sensitization, irritation, genotoxicity, and implantation testing were performed to demonstrate biocompatibility of the patient contacting materials.

## J. Conclusion

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