K063758

Teleflex Medical Incorporated
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Research Triangle Park, NC 27709 USA
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 23 2007

The ConchaTherm® Neptune™ Heated Humidifier

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

Teleflex Medical Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-361-3927
Fax: 919-361-4061

B. Contact Person

Elizabeth (Betty) Landon
Sr. Regulatory Affairs Specialist

C. Date Prepared

April 23, 2007

D. Device Name

Trade Name: The ConchaTherm® Neptune™ heated humidifier

Common Name: Humidification System

Classification Name: Respiratory Gas Humidifier (21 CFR 868.5450, Product Code BTT)

E. Device Description

The ConchaTherm® Neptune™ is designed to provide heat and moisture to the medical gases delivered to a patient via continuous flow, invasive ventilation or non-invasive ventilation. The ConchaTherm® Neptune™ heated humidifier is the main component of the Teleflex Medical ConchaTerm Humidification system, which allow gas to be delivered to a patient using various interfaces.

The ConchaTherm® Neptune™ heated humidification system consists of the ConchaTherm® Neptune™ heated humidifier, the CONCHA-COLUMN® humidifier cartridge, CONCHA sterile water reservoir, a Hudson RCI dual temperature probe, and either a non-heated wire breathing circuit or a Hudson RCI 21-volt heated-wire breathing circuit. The servo-controlled heated humidifier continuously monitors the proximal airway temperature and regulates the heat supplied to the column by the heating element, and if used, the heated-wire circuit.

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F. Indications for Use

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.

G. Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the Teleflex Medical ConchaTherm IV® (K923946) and the Fisher & Paykel MR850 (K033710). The determination of substantial equivalence for this device was based on a detailed device description, performance testing, and conformance with voluntary performance standards.

H. Summary of Testing

The ConchaTherm® Neptune™ heated humidifier has been tested and evaluated for compliance with the Standard for Safety of Medical Electrical Equipment, Part 1: General Requirements for Safety (IEC/EN 60601-1), Medical Electrical Equipment, Part 1: General Requirements for Safety, Collateral Standard, CAN/CSA C22.2 No. 601.1-M90 (IEC/EN 60601-1); Standard for Electromagnetic Compatibility and Tests (IEC/EN 60601-1-2) and Humidifiers for Medical Use-General Requirements for Humidification Systems (ISO 8185).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth Landon
Senior Regulatory Affairs Specialist
Teleflex Medical
2917 Weck Drive
Research Triangle Park, North Carolina 27709

APR 23 2007

Re: K063758
Trade/Device Name: ConchaTherm® Neptune™ Heated Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: March 16, 2007
Received: March 19, 2007

Dear Ms. Landon:

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.

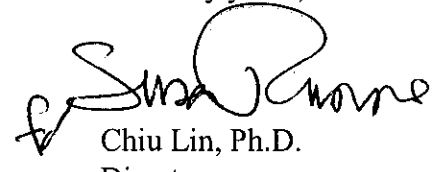
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063758

Device Name: The ConchaTherm® Neptune™

Indications for Use:

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.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K063758