K061736

Teleflex MEDICAL

AUG 18 2006

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
COMFORT FLO™ Humidification System

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

Teleflex Medical
2345 Waukegan Road
Suite 120
Bannockburn, IL 60015

B. Contact Person

Lori Hays
Senior Manager, Regulatory Affairs

C. Date Prepared

August 9, 2006

D. Device Name

Trade Name: COMFORT FLO™ Humidification System

Common Name: Humidification System

Classification Name: Respiratory Gas Humidifier

Product Code: BTT

Regulation Number: 21 CFR 868.5450

Class: II

E. Device Description

The COMFORT FLO™ Humidification System is a gas delivery system.This system is designed to deliver heated and humidified respiratory gases to spontaneously breathing adult, pediatric, infant, and/or neonatal patients. This delivery system will be used in conjunction with the ConchaTherm Heated Humidifier product line.

The COMFORT FLO™ Humidification System consists of a heated circuit, a Concha® Column, and a nasal cannula patient interface. All components of the COMFORT

FLO™ Humidification System are non-sterile with the exception of the gamma-sterilized Concha® Column.

F. Intended Use

The COMFORT FLO™ Humidification System is intended to provide a continuous flow of heated and humidified gases to spontaneously breathing patients.

G. Substantial Equivalence

The COMFORT FLO™ Humidification System is substantially equivalent to the components of the currently marketed Hudson RCI Breathing Circuits (K031383 and K010402), Hudson RCI ConchaTherm IV Heated Molecular Humidifier (K923946) and Fisher & Paykel MR850 Respiratory Humidifier (K033710). These systems have the following similarities:

1. Can be used with a heated wire assembly.

2. Intended to deliver heated humidified gas to patients.

The major differences between the COMFORT FLO™ Humidification System and the currently marketed Hudson RCI Breathing Circuits (K031383 and K010402), Hudson RCI ConchaTherm IV Heated Molecular Humidifier (K923946) and Fisher & Paykel MR850 Respiratory Humidifier (K033710) are as follows:

1. The COMFORT FLO™ Humidification System will be sold with the oxygen accessory kit. These components are not sold with the currently marketed system.

2. The COMFORT FLO™ Humidification System will contain a temperature probe wire clip not found on the currently marketed system.

3. The COMFORT FLO™ Humidification System will contain a Concha® Column which has the check valves removed to help normalize the pressure in the water bottle with the pressure in the circuit.

H. Summary of Testing

The COMFORT FLO™ Humidification System was evaluated and tested under simulated and extended use hospital conditions to demonstrate that all components can operate at or near 100% Relative Humidity, 37°C, and a rate of 1 to 40 LPM for up to 14 days without loss of functional integrity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Teleflex Medical
C/O Mr. Neil E. Devine
Responsible Third Party Official
Tntertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K061736
Trade/Device Name: COMFORT FLO™ Humidification System
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 3, 2006
Received: August 4, 2006

Dear Mr. Devine:

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 (301) 443-6597 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):

Device Name: COMFORT FLO™ Humidification System

Indications For Use:

To provide a continuous flow of heated and humidified gas to spontaneously breathing patients.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K061736