K080230

Non-Confidential Summary of Safety and Effectiveness

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29-Jan-08

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JUN - 9 2008

Official Contact: Michael Crader, VP Global RA/QA

Proprietary or Trade Name: Neb-U-Mask® System

Common/Usual Name: Nebulizer

Classification Name: Nebulizer (direct patient interference)
CAF – 868.5630

Predicate Devices: B&B Technology – Hope nebulizer - K980407
DHD Healthcare – Trust nebulizer – K040718
Teleflex Medical /Hudson RCI – Micro Mist Nebulizer – K930525

Device Description:

The Neb-U-Mask® System is intended to be with oxygen and oxygen-helium (Heliox) mixtures that include a non-rebreathing mask connected to a wye adaptor featuring a valved port. This valve allows a small volume nebulizer to be connected / disconnected to the wye adapter for drug administration without interrupting primary medical gas flow to patient. Attached to the adaptor is a reservoir bag and a nebulizer, both linked to the gas sources with delivery tubing allowing clinicians to independently control the flow to each side.The Neb-U-Mask® System is comprised of:

- Non-rebreathing oxygen mask (several sizes)
- Wye is valved,
  - contains an MDI port,
  - connectors for nebulizer and reservoir, and
  - inlet port for Heliox mixture
- Delivery tubing
  - Heliox / Oxygen to nebulizer
  - Heliox / oxygen to ported wye
- Small volume nebulizer

Indications for Use: For the delivery of high concentrations of oxygen or Heliox gas mixtures in combination with aerosolized medications and diagnostic formulations. This device has not been tested for use with Pentamidine or the combination of Heliox and metered dose inhaler.

Patient Population: Adult and pediatric

Environment of Use: To be used under medical supervision in hospitals, pre-hospital (EMS), nursing homes, extended care facilities and outpatient clinics.

Contraindications: None

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Attribute	Proposed Neb-U-Mask® System	Teleflex Medical / Hudson RCI nebulizer K930525	B&B Hope K980407	DHD Trust K040718
Indications for Use (all are not for use with pentamidine)	For the delivery of high concentrations of oxygen or Heliox gas mixtures in combination with aerosolized medications. This device has not been tested for use with Pentamidine or the combination of Heliox and metered dose inhaler. Indication for high concentrations of oxygen via a non-rebreather mask is an exempt indication	Used as a nebulizer	High output nebulizer to be used to deliver aerosolized medications and diagnostic formulas.	Uses as a nebulizer aerosolized medications and diagnostic formulations
Used with Heliox 80/20 and 70/30 mixtures	Yes	No	Yes	Yes
Environments of use home care, nursing home, sub-acute institutions or hospitals, pre-hospital (EMS)	Yes	Yes	Yes	Yes
Patient population	Pediatric Adult	Not listed	Asthma, pneumonia, COPD and general conditions	Asthma, pneumonia, COPD and general conditions
Nebulizer technology	Jet nebulizer	Jet nebulizer	Jet nebulizer	Jet nebulizer
Single patient, disposable	Yes	Yes	Yes	Yes
Operational Flow Rates	Standard oxygen 8 Lpm Heliox up to 12 Lpm	Standard oxygen 8 Lpm	Not listed	Not listed
Used with face mask	Yes	Yes	Yes	Yes
Materials Common materials in contact with gas and fluid pathway	Yes	Yes	N/A	N/A
Particle size characterization via Cascade Impactor	Yes	Yes	N/A	N/A

Differences Between Other Legally Marketed Predicate Devices:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Teleflex Medical, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

JUN - 9 2008

Re: K080230
Trade/Device Name: Neb-U-Mask® System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 2, 2008
Received: June 3, 2008

Dear Mr. Dryden:

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.

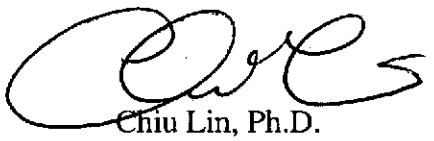
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number: _____ (To be assigned)

Device Name: Neb-U-Mask® System

Indications for Use:

For the delivery of high concentrations of oxygen or Heliox gas mixtures in combination with aerosolized medications and diagnostic formulations. This device has not been tested for use with Pentamidine or the combination of Heliox and metered dose inhaler.

Patients include pediatric and adult.

Environment of Use:
To be used under medical supervision in hospitals, pre-hospital (EMS), nursing homes, extended care facilities and outpatient clinics.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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: K080230