K093913

510(k) Summary
Page 1 of 5
30-Mar-10

APR - 8 2010

Mercury Medical, Inc.
11300 - 49th St. North
Clearwater, FL 33762-4807

Tel – (727) 573-0088
Fax – (727) 571-3922

Official Contact: Jeff Ratner – VP Engineering and Quality Assurance

Proprietary or Trade Name: Mercury Medical T-Piece Resuscitator (Neo-Tee™)

Common/Usual Name: Infant T-Piece Resuscitator

Classification Name/Code: BTL – powered emergency ventilator
CFR 868.5925

Device: Mercury Medical T-Piece Resuscitator

Predicate Devices: GE – Giraffe and Panda – K070210
Fisher & Paykel – NeoPuff – K892885

Device Description:
The Mercury Medical T-Piece Resuscitator (Neo-Tee™) is a gas power resuscitator for use with neonates / infants < 10 kg (22 lb).

It is a simple T-piece, with a manometer and the ability to adjust Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP). It incorporates a pressure relief valve for excessive pressure.

The Mercury Medical T-Piece Resuscitator (Neo-Tee™) can be connected to the patient via a face mask or endotracheal tube.

Indications for Use:
The (Neo-Tee™) T-Piece Resuscitator is a gas powered emergency resuscitator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. It is intended for use with neonates and infants weighing less than 10kg (22 lb).

Environment of Use: Hospital, delivery suites, ICU and Nursery settings

Summary of substantial equivalence

	Proposed **Mercury Medical T-Piece Resuscitator (Neo-Tee™)**	**Predicate** **K070210 GE Giraffe and Panda**	**Predicate** **K892885 F&P NeoPuff**
Indications for Use	The Neo-Tee™ T-Piece Resuscitator is a gas powered emergency resuscitator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. It is intended for use with neonates and infants weighing less than 10kg (22 lb).	Provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen and air/oxygen mixtures and/or manual ventilation to the infant. These are clinical practices that represent the established standard or care.* Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide. * As stated in collaborative guidelines written by the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) in the Textbook of Neonatal Resuscitation, 5th Edition.	Manually operated, gas powered resuscitator which provides controlled and accurate resuscitation of newborn babies
Environment of use	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU
Patient Population	Infant and neonates < 10 kg	Infant < 10 kg	Infant < 10 kg
Prescriptive	Persons trained in infant / neonate resuscitation	For professional use only, by trained clinicians.	Persons trained in infant resuscitation

	Proposed **Mercury Medical T-Piece Resuscitator (Neo-Tee™)**	**Predicate** **K070210 GE Giraffe and Panda**	**Predicate** **K892885 F&P NeoPuff**
Patient connection	Face mask ET tube	Face mask ET tube	Face mask ET tube
Features and Performance Characteristics			
Gas flow provided by	Wall gas or cylinder	Wall gas or cylinder	Wall gas or cylinder
Components	T-piece configuration Manometer Adjustable PIP Adjustable PEEP Masks	T-piece configuration Manometer Adjustable PIP Adjustable PEEP Masks	T-piece configuration Manometer Adjustable PIP Adjustable PEEP Masks
Manometer range	Up to 60 cmH_2O Cleared under K032593	-10 to 80 cm H_2O	-20 to 80 cm H_2O
Manometer accuracy	+/- 3 cm H_2O up to 15 cm H_2O +/- 5 cm H_2O > 15 cm H_2O	+/- 5% of full scale	Not specified
Peak Inspiratory Pressure (PIP)	0-40 cm H_2O @ 15 Lpm	Maximum PIP 45 +/- 5 cm H_2O	@ 8 Lpm – 2 to 73 cm H_2O @ 10 Lpm – 2 to 80 cm H_2O
Positive End-Expiratory Pressure (PEEP)	@ 5 Lpm – < 2.1 cm H_2O @ 8 Lpm – < 5.0 cm H_2O @ 10 Lpm – < 7.2 cm H_2O @ 15 Lpm – < 14.6 cm H_2O	@ 5 Lpm – < 5 cm H_2O @ 8 Lpm – < 5 cm H_2O @ 10 Lpm – < 5 cm H_2O @ 15 Lpm – < 6 cm H_2O	@ 5 Lpm – 1 to 5 cm H_2O @ 8 Lpm – 1 to 9 cm H_2O @ 10 Lpm – 2 to 15 cm H_2O @ 15 Lpm – 3 to 25 cm H_2O
Operating time based on e-cylinder	@ 15 Lpm ~ 44 minutes	@ 5 Lpm – 121 minutes @ 10 Lpm – 77 minutes @ 15 Lpm – 54 minutes	5 to 50 Lpm – 50 minutes
Maximum pressure relief	40 cm H_2O @ 15 Lpm		40 cm H_2O
Air / Oxygen mixture	Up to 100% O_2	21 to 100% O_2	Not specified
Maximum gas flow rate	15 Lpm	15 Lpm	15 Lpm

	Proposed **Mercury Medical T-Piece Resuscitator (Neo-Tee™)**	**Predicate** **K070210 GE Giraffe and Panda**	**Predicate** **K892885 F&P NeoPuff**
Warnings	1. Incorrect operation of this device can be hazardous. 2. Do not use in the presence of flammable materials and ensure that no sources of ignition are present while the device is in use. Fire hazards are possible in oxygen enriched environments. 3. Users should release the T-piece (manual control) as soon as the breath is delivered. Failure to do so will result in an extended breath, which may prevent exhalation. 4. Do not leave patient unattended when device is in use. 5. The recommended gas flow range is from 1 – 15 LPM. DO NOT EXCEED 15 LPM.	Not available	1. Ensure no smoking, naked flames or sources of ignition are present while the unit is in use. 2. Recommended operating gas flow range 5 to 15 Lpm. Do not attempt to use a higher flow than 15 Lpm.

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

The Mercury Medical T-Piece Resuscitator (Neo-Tee™) is viewed as substantially equivalent to the predicate devices because:

Indications –

- Similar to predicate – F&P – NeoPuff – K892885

Technology –

- Similar technology and design –
  - GE Giraffe – K070210 and F&P – NeoPuff – K892885

Materials –

- The materials in patient contact are identical to predicate devices manufactured by Mercury Medical.

Environment of Use –

- Identical to predicate –
  - GE Giraffe – K070210 and F&P – NeoPuff – K892885

Performance Testing –

The following performance / bench tests were performed and shown to demonstrate that the Mercury Medical T-piece Resuscitator (Neo-Tee™) either met the requirements of industry standard, ISO 10651:2006 or were substantially equivalent to the predicate devices.

Test	Test requirements
Vomitus Resistance	Must subsequently pass Oxygen Concentration, Inspiratory Resistance, Expiratory Resistance, PEEP, Delivered Volume and Pressure Limitation tests
Water Immersion	Resuscitator must continue to function within the tolerances for normal use
Oxygen Concentration	Volumetric concentration of oxygen must be > 85%
Inspiratory Resistance	Pressure at patient connection port must be > -6 cm H_2O with inspiratory airflow of 6 L/min
Expiratory Resistance	Pressure at patient connection port must be < 6 cm H_2O with expiratory airflow of 6 L/min
PEEP Test	PEEP must be < 2 cm H_2O during Oxygen Concentration Test
Delivered Volume	Delivered volume must be < 20 mL @ C1, R200 and > 3.75 mL @ C10, R20
Pressure Limitation	Pressure must not exceed 60 cm H_2O @ 60 L/min
Storage/Operating Conditions	Must subsequently pass Delivered Volume and Pressure Limitation tests
Drop	Resuscitator must continue to function within the tolerances for normal use

The (Neo-Tee™) T-piece resuscitator met all the performance requirements as outline above and thus can be found to either comply with ISO 10651:2006 or is equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

APR - 8 2010

Re: K093913
Trade/Device Name: Mercury Medical T-Piece Resuscitator (Neo-Tee™)
Regulation Number: 21CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: December 19, 2009
Received: December 22, 2009

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K093913

Device Name: Mercury Medical T-Piece Resuscitator (Neo-Tee™)

Indications for Use:

The Neo-Tee™ T-Piece Resuscitator is a gas powered emergency resuscitator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. It is intended for use with neonates and infants weighing less than 10kg (22 lb).

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: K093913