DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2014

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

Re: K142096
Trade/Device Name: T-Piece Resuscitator
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: August 14, 2014
Received: August 15, 2014

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 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.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142096

Device Name

T-piece Resuscitator

Indications for Use *(Describe)*

The 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 patients weighing greater than 10kg (>22lb).

Environment of Use – Hospital, sub-acute facilities, and pre-hospital (EMS)

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)*

510(k) Summary

14-Oct-14

Mercury Medical, Inc.
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Clearwater, FL 33762-4807

Tel – (727) 573-0088
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Official Contact: Jeff Ratner – VP Engineering and Quality Assurance

Proprietary or Trade Name: T-Piece Resuscitator

Common/Usual Name: Powered emergency ventilator

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

Device: T-Piece Resuscitator

Predicate Devices: NeoForce – ISPIRA - K092085
Mercury – NeoTee™ - K093913

Device Description:
The Mercury T-Piece Resuscitator is manually operated, gas powered resuscitator for use with patients greater than 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 T-Piece Resuscitator can be connected to the patient via a face mask, Supraglottic airway or endotracheal tube**.**

Indications for Use:
The 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 patients weighing greater than 10kg (>22 lbs.).

Environment of Use: Hospital, sub-acute facilities, and pre-hospital (EMS)

Substantial Equivalence:
The Mercury T-Piece Resuscitator is a similar design T-piece resuscitation system to our own reference device, Mercury NeoTee™ (K093913) and with the NeoForce ISPIRA (K092085) for the indications for use and patient population. We will provide information which demonstrates that the proposed device is substantially equivalent to the predicates.

Table 5.1 lists the similarities and differences of the predicate, NeoForce ISPIRA (K092085) and the proposed device. While **Table 5.2** compares the reference device, Mercury NeoTee™ (K093913) which has the identical design of patient circuit but is indicated for neonate / infant populations and a more limited environment of use.

Summary of substantial equivalence

Table 5.1 - Table of the Similarities and Differences of Proposed Device vs. the Predicate

	Proposed **Mercury Medical T-Piece Resuscitator**	**Predicate** **NeoForce ISPIRA** **K092085**
Indications for Use	The T-Piece Resuscitator is a powered emergency ventilator 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 patients greater than 10kg (>22 lbs.).	The NeoForce ISPIRA Resuscitation System is a manually operated, gas powered resuscitator intended for controlled and accurate pulmonary resuscitation and emergency respiratory support of pediatric and adult patients with a body weight of more than 22 lbs. (10 kg) in the hospital, pre-hospital (EMS), and sub-acute / alternate site facility environments via face mask, laryngeal mask or endotracheal tube. The device is also intended to provide CPAP to spontaneously breathing patients in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via face mask, laryngeal mask or endotracheal tube.
Environment of use	Hospital, sub-acute facilities, and pre-hospital (EMS)	Hospital, pre-hospital (EMS), and sub-acute / alternate site facility environments
Patient Population	Patients greater than 10 Kg (>22 lbs.)	Patients greater than 10 Kg (>22 lbs.)
Prescriptive	Persons trained in resuscitation	Persons trained in resuscitation
Patient connection	Face mask Supraglottic airway Endotracheal Tube	Face mask Supraglottic airway (LMA) Endotracheal Tube
Features and Performance Characteristics		
Gas flow provided by	Wall gas or cylinder	Wall gas or cylinder
Components	• Hand-piece which is a T-piece configuration with Manometer • Corrugated tubing and connector • Control Panel which allows for PIP and PEEP adjustments • Oxygen tubing • Masks (optional)	• T-piece configuration • Manometer part of controller • Corrugated tubing and connectors • Controller which allows for PIP, PEEP, and CPAP adjustments • Tubing to monitor pressure Oxygen delivered via corrugated hose • Mask has some CPAP features
Ventilation Frequency	Manually delivered by the user up to 60 BPM	Manually delivered by the user up to 60 BPM
Maximum pressure relief	60 cm H_2O Factory set at 40 cm H_2O	5-80 cm H_2O. Factory set at 40 cm H_2O

	Proposed **Mercury Medical T-Piece Resuscitator**	**Predicate** **NeoForce ISPIRA** **K092085**
Delivered Pressure	Up to 60 cm H_2O	5 to 80 cm H_2O
CPAP	Not offered but offers PEEP Identical to K093913 – Mercury NeoTee™	5 -15 cm H_2O@ 8-12 lpm flow
Delivered Volume	60 – 700 ml with flow rates between 5 – 35 lpm	190 - 675 ml with flow rates between 4 - 36 lpm
Inspiratory resistance	2 cm H_2O at minimum PEEP setting @ 60 lpm	Less than - 5 cm H_2O
Expiratory resistance	2.4 cm H_2O at minimum PEEP setting @ 60 lpm	Less than + 5 cm H_2O
Oxygen concentration with optional blender	21 – 98% based upon blender setting	21 – 100% based upon blender setting
Manometer range	Up to 60 cmH_2O Cleared under K954486	-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	+/- 2 cm H_2O
Peak Inspiratory Pressure (PIP)	0-60 cm H_2O	5-80 cm H_2O
Positive End-Expiratory Pressure (PEEP)	0 to 60 cm H_2O	Not offered. Use CPAP instead
Operational gas flow rate	0 – 35 lpm	0 – 60 lpm
Operational time with 400 L cylinder	@ 35 lpm – 11 minutes	@ 36 lpm – 10 minutes
Dead space of circuit	< 7.5 ml	< 15 ml
Operating Temperature range	-18 to 60^oC	10 to 40^oC
Storage Temperature	-40 to 50^oC	-20 to 60^oC
Immersion resistance	Temporary submersion of circuit does not affect functionality	Temporary submersion of circuit does not affect functionality
Reusable	No	Yes
Standards	ISO 10651-5	ISO 10651-5

Table 5.2 - Table of the Similarities and Differences of Proposed vs. the Reference NeoTee™

	Proposed **Mercury Medical T-Piece Resuscitator**	**Reference** **Mercury NeoTee™** **K093913**
Indications for Use	The T-Piece Resuscitator is a powered emergency ventilator 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 patients greater than 10kg (>22 lbs.).	The Mercury Medical T-Piece Resuscitator is a powered emergency ventilator 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 lbs.).
Environment of use	Hospital, sub-acute facilities, and pre-hospital (EMS)	Hospital, delivery suites, nursery, ICU
Patient Population	Patients greater than 10 Kg (>22 lbs.)	Patients less than 10 Kg (<22 lbs.)
Prescriptive	Persons trained in resuscitation	Persons trained in infant / neonate resuscitation
Patient connection	Face mask Supraglottic airway Endotracheal Tube	Face mask Endotracheal Tube
Features and Performance Characteristics		
Gas flow provided by	Wall gas or cylinder	Wall gas or cylinder
Components	• Hand-piece which is a T-piece configuration with Manometer • Corrugated tubing and connector • Control Panel which allows for PIP and PEEP adjustments • Oxygen tubing • Masks (optional)	• Hand-piece which is a T-piece configuration with Manometer • Corrugated tubing and connector • Control Panel which allows for PIP and PEEP adjustments • Oxygen tubing • Masks (optional)
Maximum pressure relief	60 cm H_2O	40 cm H_2O
Delivered Pressure	Up to 60 cm H_2O	Up to 40 cm H_2O
Delivered Volume	60 – 700 ml with flow rates between 5 – 35 lpm	15-200 ml
Manometer range	Up to 60 cmH_2O (K954486)	Up to 60 cmH_2O (K954486)
Manometer accuracy	+/- 3 cm H_2O up to 15 cm H_2O +/- 5 cm H_2O > 15 cm H_2O	+/- 3 cm H_2O up to 15 cm H_2O +/- 5 cm H_2O > 15 cm H_2O
Inspiratory resistance	2 cm H_2O at minimum PEEP setting @ 60 lpm	0.4 cm H_2O at minimum PEEP setting @ 6 lpm
Expiratory resistance	2.4 cm H_2O at minimum PEEP setting @ 60 lpm	0.5 cm H_2O at minimum PEEP setting @ 6 lpm
Peak Inspiratory Pressure (PIP)	0-60 cm H_2O	0-40 cm H_2O @ 15 Lpm

	Proposed **Mercury Medical T-Piece Resuscitator**	**Reference** **Mercury NeoTee™** **K093913**
Positive End-Expiratory Pressure (PEEP)	0-60 cm H_2O	2 cmH_2O at 2.5 lpm up to 15 cm H_2O @ 15 lpm
Operational time with 400 L cylinder	@ 35 lpm – 11 minutes w/ 400 L @ 35 lpm ~ 19 min with 660 L cylinder	@ 15 lpm – 26 minutes w/ 400L @ 15 lpm – 44 minutes w/ 660L
Operational gas flow rate	0 – 35 lpm	0 – 15 lpm
Dead space of circuit	< 7.5 ml	< 3.48 ml

Substantial Equivalence Rationale

The Mercury T-Piece Resuscitator is viewed as substantially equivalent to the predicate devices because:

Indications – Identical indications for use to our reference device, NeoTee™ (K093913). Similar to the predicate NeoForce (K092085), which are is a gas powered emergency ventilator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. The environments of use are different as the proposed device as the predicate was specifically designed for neonate use.
Discussion – The differences in indications for use between the reference device, NeoTee™ (K093913), patient population and environment differences are covered with the NeoForce™ (K092085).

Technology – The technology is identical to the reference NeoTee™ (K093913) which includes all the features and components.
Discussion –The only difference between the proposed T-piece and the reference NeoTee™ is the size of the PEEP cap to accommodate high gas flow for adults. The patient connector for the proposed device is 15mm ID / 22mm OD to allow for connection to standard face mask with 22 mm ID fittings as well as endotracheal tubes with 15 mm OD fittings vs. the reference NeoTee™ (K093913) only has a 15mm ID connector which allows it to connect to endotracheal tubes and face mask with 15 mm OD fittings. These differences do not raise any new safety concerns.

Materials – The materials in patient contact are identical to the NeoTee™ device manufactured by Mercury Medical**.**
Discussion – The materials are identical and the patient contact is also identical to the reference NeoTee™ (K093913). The manufacturing, handling and processing are identical to the reference device and we can make a certification claim.

Non-clinical Testing

We performed a number of tests to demonstrate the performance of the proposed device to the reference or predicate devices.

Bench testing – We performed applicable testing per ISO 10651-5 for gas powered resuscitators. These tests included:

- Vomitus Resistance
- Water Immersion
- Oxygen Concentration
- Inspiratory Resistance
- Expiratory Resistance
- PEEP Test
- Delivered Volume
- Pressure Limitation
- Storage/Operating Conditions
- Drop

Discussion – We have demonstrated that the T-Piece Resuscitator meets the performance and design specifications requirements as outlined in requirements and specifications as outlined in ISO 10651-5 – Particular Requirements for Basic Safety and Essential Performance for Gas Powered Resuscitators.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.