November 16, 2018

Ventlab, LLC
Rob Yamashita
Director of Regulatory Affairs
2710 Northridge Drive NW - Suite A
Grand Rapids, Michigan 49544

Re: K173373
Trade/Device Name: SafeT T-Piece Resuscitator
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: October 11, 2018
Received: October 17, 2018

Dear Rob Yamashita:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amy K. Levelle -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173373

Device Name
Ventilator, Emergency, Powered (Resuscitator)

Indications for Use *(Describe)*

The SafeT 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 10 kg (22 lb).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	10/11/2018
Proprietary or Trade Name:	SafeT T-Piece Resuscitator
Common/Usual Name:	Powered emergency ventilator
Classification Code/Name:	BTL – Powered emergency ventilator
	CFR 868.5925
Proposed Regulatory Class:	Class II
Official Contact:	Rob Yamashita
	Director of Regulatory Affairs
	Ventlab, LLC
	2710 Northridge Dr. NW, Suite A
	Grand Rapids, MI 49544 USA
	Phone: (616) 259-8373
Predicate Devices:	Primary – Mercury Medical Neo-Tee™ – K093913
	Reference – Fisher & Paykel NeoPuff™ – K892885

Device Description

The SafeT T-Piece Resuscitator is a single-use, non-sterile, manually operated, gas-powered resuscitator for use with patients less than 10 kg (22 lb).

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

The T-Piece resuscitator can be connected to the patient via a face mask or tube.

The subject device consists of several components:

- T-Piece patient valve with variable PEEP dial and integrated manometer
- Adjustable inspiratory pressure controller
- 40 cm H_2O pressure relief valve
- 7’ Oxygen tubing with a red universal (Fits-all) connector
- 20” x 10 mm circuit tubing
- Face mask

Indications for Use

The SafeT 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 10 kg (22 lb).

Technological Characteristics

The SafeT T-Piece Resuscitator is a circuit intended for emergency resuscitation of neonates and infants. Oxygen or blended gas flows through the circuit, which is composed of an inspiratory pressure controller and a T-Piece patient valve. The inspiratory pressure controller allows adjustment of Peak Inspiratory Pressure (PIP). This inspiratory pressure controller has an integral pressure relief valve, which prevents the inspiratory pressure from exceeding 40 cm H_2O.

The T-Piece patient valve has an integral manometer which reads and displays both Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP). The T-Piece patient valve consists of a PEEP dial, which allows adjustment of Positive End-Expiratory Pressure (PEEP), and a patient port for attachment to face masks and tubes. The subject device contains a face mask.

Substantial Equivalence Discussion

The following table compares SafeT to the predicate device with respect to its physical state, structure, materials, mechanical properties, indications for use, biocompatibility and performance testing, and provides detailed information regarding the basis for the determination of substantial equivalence. The reference device is also included in this table for comparative purposes.

Substantial Equivalence Comparison Table

	SunMed SafeT	Mercury Medical Neo-Tee	Fisher & Paykel NeoPuff	Similarities / Differences
Manufacturer	SunMed	Mercury Medical	Fisher & Paykel	-
510(k)	Current submission	K093913	K892885	-
Device Type	Subject Device	Primary Predicate	Reference Device	-
Classification	II	II	II	Same
Product Code	BTL	BTL	BTL	Same
Regulation Number	868.5925	868.5925	868.5925	Same
Applicable Standards	ISO 10651-5, Lung Ventilators for Medical Use – Particular Requirements for Basic Safety and Essential Performance	ISO 10651-5, Lung Ventilators for Medical Use – Particular Requirements for Basic Safety and Essential Performance	ISO 10651-5, Lung Ventilators for Medical Use – Particular Requirements for Basic Safety and Essential Performance	Same

	ISO 5356-1, Anaesthetic and Respiratory Equipment – Conical Connectors ISO 5367, Breathing Tubes Intended for Use with Anaesthetic Apparatus and Ventilators BS EN 13544-2, Respiratory Therapy Equipment, Tubing and Connectors ISO 10651-4, Lung ventilators - Part 4: Particular requirements for operator powered resuscitators	ISO 5356-1, Anaesthetic and Respiratory Equipment – Conical Connectors ISO 5367, Breathing Tubes Intended for Use with Anaesthetic Apparatus and Ventilators BS EN 13544-2, Respiratory Therapy Equipment, Tubing and Connectors	ISO 5356-1, Anaesthetic and Respiratory Equipment – Conical Connectors ISO 5367, Breathing Tubes Intended for Use with Anaesthetic Apparatus and Ventilators BS EN 13544-2, Respiratory Therapy Equipment, Tubing and Connectors	
Indications of Use	The SafeT 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).	The Neo-Tee T-Piece Resuscitator is a gas powered emergency resuscitator intended to provide emergency 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.)	Manually operated, gas powered resuscitator which provides controlled and accurate resuscitation of newborn babies	The subject and predicate device have the same intended use.
Patient Connection	Face Mask & ET Tube	Face Mask & ET Tube	Face Mask & ET Tube	Same
Environment of Use	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU	Same

Patient Population	Infants and neonates < 10 kg (22 lb)	Infants and neonates < 10 kg (22 lb)	Infants < 10 kg (22 lb)	Same
Prescriptive	Persons trained in infant / neonate resuscitation	Persons trained in infant / neonate resuscitation	Persons trained in infant / neonate resuscitation	Same
Reusable	Single use, disposable	Single use, disposable	Single use, disposable (T-Piece Circuit)	Same
Useful Life	less than 24 hours	less than 24 hours	Not specified	Same
Shelf Life	2 years	2 years	Not specified	Same
Design	Includes PIP controller, tubing, and patient valve with manometer (with PEEP adjustment)	Includes PIP controller, tubing, and patient valve with manometer (with PEEP adjustment)	Includes resuscitator unit (with integral PIP controller) and accessories - T-Piece Circuit, Masks, Gas Supply Line (i.e. tubing)	The subject and predicate device have the same design.
Materials	ABS and Polypropylene (patient valve, PEEP Dial, Integrated Manometer, Patient Port, PIP Dial, Inspiratory Pressure Controller), Silicone (Manometer diaphragm), Medical Grade Stainless Steel (manometer spring), Phosphor bronze (PEEP spring), and flexible PVC (mask and circuit tubing)	Common plastics and metals	Common plastics and metals	The materials used in the subject and predicate device are similar and well understood.
Energy Source	Gas powered (compressed O_2 or gas blend)	Gas powered (compressed O_2 or gas blend)	Gas powered (compressed O_2 or gas blend)	The subject and predicate device have the same energy source.
Gas Flow Provided by	Wall gas or cylinder	Wall gas or cylinder	Wall gas or cylinder	Same

Cycling Pressure Range	0 to 40 cm H_2O	0 to 40 cm H_2O	0 to 40 cm H_2O (Max Pressure Relief Factory Set @ 40 cm H_2O)	Same
Ventilatory Frequency	Up to 60 breaths/min (ISO 10651-5 Table 1)	Up to 60 breaths/min (ISO 10651-5 Table 1)	Up to 60 breaths/min (ISO 10651-5 Table 1)	Same
Dead Space (no accessory attached) - Avg. value from Gas Trace Method (ISO 10651-4 A.4.10)	3.07 ml	2.67 ml	Not specified	The subject and predicate device have similar dead space. In ISO 10651-5 for manual resuscitators, allowable dead space is 30% of the minimum delivered tidal volume of 18 mL for a total of 5.4 mL.
Dead Space (18 Fr endotracheal tube - worst case) - Avg. value from Gas Trace Method (ISO 10651-4 A.4.10)	7.4 ml	6.9 ml	Not specified	The subject and predicate device have similar dead space with similar ET tubes and do not raise questions of safety and effectiveness.
Dead Space (with infant face mask - worst case) - Avg. value from Gas Trace Method (ISO 10651-4 A.4.10)	29.7 ml	29.4 ml	Not specified	The subject and predicate device have similar dead space with similar infant face mask and do not raise questions of safety and effectiveness.
Dead Space (with neonate face mask) - Avg. value from Gas Trace Method (ISO 10651-4 A 4.10)	22.2 ml	19.7 ml	Not specified	The subject and predicate device have similar dead space with similar neonate face masks and do not raise questions of safety and effectiveness.

Operational Gas Flow Rate (input gas flow range)	5 - 15 LPM	5 - 15 LPM	5 L/min (min) - 15 L/min (max)	Same
Peak Inspiratory Flow	15 LPM	15 LPM	15 LPM	Same
Manometer Range	Up to 60 cm H_2O	Up to 60 cm H_2O	- 10 to 80 cm H2O	The subject and predicate device have the same manometer range.
Manometer Accuracy	Up to 15 cm H_2O - ± 3 cm H_2O Greater than 15 cm H_2O - ± 5 cm H_2O	Up to 15 cm H_2O - ± 3 cm H_2O Greater than 15 cm H_2O - ± 5 cm H_2O	+/- 2.0% of Full Scale Deflection	The subject and predicate device have the same manometer accuracy.
Peak Inspiratory Pressure (PIP)	0 to 40 H_2O @ 15 LPM	0 to 40 H_2O @ 15 LPM	@ 5 L/min - 2 to 70 cm H_2O @ 8 L/min - 3 to 72 cm H_2O @ 10 L/min - 4 to 73 cm H_2O @ 15 L/min - 8 to 75 cm H_2O	Same
Maximum Pressure Relief (high pressure pop-off)	40 cm H_2O	40 cm H_2O	Max Pressure Relief Factory Set @ 40 cm H_2O	Same
Visual or Audible Indication of High Pressure	Audible	Audible	Not specified	Same
Peak End-Expiratory Pressure (PEEP) Range	At 5 LPM, 1 to 3 cm H_2O At 8 LPM, 2 to 7 cm H_2O At 10 PLM, 4 to 12 cm H_2O At 15 LPM, 9 to 23 cm H_2O	At 5 LPM, up to approx. 2 cm H_2O At 8 LPM, up to approx. 6 cm H_2O At 10 PLM, up to approx. 9 cm H_2O At 15 LPM, up to approx. 15 cm H_2O	At 5 L/min - 1 to 5 cm H2O At 8 L/min - 1 to 9 cm H2O At 10 L/min - 2 to 15 cm H2O At 15 L/min - 3 to 25 cm H2O	The subject device range and the predicate device's upper limit is different, however, substantially equivalent. The subject device range falls within those of the reference device and do not raise questions of safety and effectiveness.
Delivered Oxygen Concentration	Up to 100% O_2	Up to 100% O_2	Up to 100% depending on gas supply	Same

Oxygen Concentration with Optional Blender	Up to 100% O_2	Up to 100% O_2	Not specified	Same
Inspiratory Resistance	1.2 cm H_2O at minimum PEEP setting @ 6 LPM	1.6 cm H_2O at minimum PEEP setting @ 6 LPM	Not specified	Similar
Expiratory Resistance	0.8 cm H_2O at minimum PEEP setting @ 6 LPM	0.2 cm H_2O at minimum PEEP setting @ 6 LPM	Not specified	Similar
Storage Temperature Range	- 40° C to +60° C, up to 95% RH	- 40° C to +60° C, up to 95% RH	- 10 to 50 °C (+14 to +122 °F), up to 95% humidity	Same
Operating Temperature Range	- 18° C to +50° C, up to 95% RH	- 18° C to +50° C, up to 95% RH	- 18 to 50 °C (- 0.4 to +122 °F), up to 95% humidity	Same
Immersion Resistance	Meets ISO 10651-5 Section 6.3.3	Meets ISO 10651-5 Section 6.3.3	Not specified	Same
Operating time (E cylinder)	660 L @ 15 LPM ~ 47 min.	660 L @ 15 LPM ~ 44 min.	400 L @ 8 L/min - 50 minutes	Similar
Size	Meets ISO 10651-5 Section 6.4.1 - passes through 300mm X 600mm opening	Meets ISO 10651-5 Section 6.4.1 - passes through 300mm X 600mm opening	Height 250 mm Width 200 mm	Similar
Mass	Meets ISO 10651-5 Section 6.4.2 - 120 grams (entire resuscitator), 40 grams (patient valve)	Meets ISO 10651-5 Section 6.4.2 - 83 grams	1.9 kg	Similar
Patient Connection	ISO 5356-1 - 15 mm taper female	ISO 5356-1 - 15 mm taper female	ISO 5356-1 - 15 mm taper female	Same
Universal Supply Connection	CGA 1240 Oxygen DISS standard	CGA 1240 Oxygen DISS standard	CGA 1240 Oxygen DISS standard	Same

Indications for Use – The subject device indications for use is the same as the predicate device. Both devices are gas-powered emergency ventilators intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. The patient populations are identical as both are specifically designed for neonate and infant use.

Technological Characteristics – Features, Material, and Principles of Operation

Principles of Operation and Features

The principles of operation for the subject and predicate devices are identical. The setup and operation of the devices are equal. Further, the operation of the PIP dial and PEEP dial for the subject and predicate devices are also equal.

For both the subject and predicate T-Piece Resuscitators, Oxygen or blended gas flows through the circuit, which is composed of an inspiratory pressure controller and a T-Piece patient valve. The subject and predicate devices have an inspiratory pressure controller that allows adjustment of Peak Inspiratory Pressure (PIP). This inspiratory pressure controller has an integral pressure relief valve, which prevents the inspiratory pressure from exceeding 40 cm H_2O.

The T-Piece patient valve has an integral manometer which reads and displays both Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP). The T-Piece patient valve consists of a PEEP dial, which allows adjustment of Positive End-Expiratory Pressure (PEEP), and a patient port for attachment to face masks and endotracheal tubes. Both the subject and predicate devices contain a face mask.

Both the subject and predicate devices are connected to a hospital flowmeter that is connected to an Oxygen or blended gas source. Gas flow is then adjusted with a flowmeter.

Additionally, the subject and predicate devices are of similar size and mass.

Material

The subject device materials are ABS and Polypropylene (patient valve, PEEP Dial, Integrated Manometer, Patient Port, PIP Dial, Inspiratory Pressure Controller), Silicone (Manometer diaphragm), Medical Grade Stainless Steel (manometer spring), Phosphor bronze (PEEP spring), and flexible PVC (mask and circuit tubing). The subject device has passed all performance testing to the applicable standards.

Operating Time

The predicate device has an e-cylinder operating time of 44 minutes @15 LPM. The subject device has an e-cylinder operating time of 47 minutes at 15 LPM. The subject device's operating time is three minutes longer than the predicate device. This difference of + 3 minutes for our subject device does not impact substantial equivalence because the purpose of the e-cylinder is to provide backup oxygen in case the pipeline supply fails.

Face Mask Accessory

The six different face masks included with the subject device are made of flexible PVC. These materials are similar to the predicate device face masks.

The six different masks included with the subject device are sized for neonate and infants weighing less than 10 kg (22 lb). Likewise, the predicate device utilizes similar sizes. These sizes of masks are aligned with the subject and predicate Indications for Use Statement.

Peak End-Expiratory Pressure (PEEP) Flow Range

The PEEP flow range for the subject device is substantially equivalent to the predicate device (Mercury Medical NeoTee) and the reference device (Fisher & Paykel NeoPuff). The subject device upper PEEP delivery is 3, 7, 12, and 23 cm H_2O and the predicate device upper PEEP delivery

is 2, 6, 9, and 15 cm H_2O at all four stated flow rates. Further, the subject device PEEP range is within the reference device PEEP range at all four stated flow rates.

Resuscitator Dead Space

The head-to-head testing, to ISO 10651-4 A.4.10 Resuscitator dead space, demonstrated the subject device is substantially equivalent to the predicate device (Mercury Medical Neo-Tee) as it relates to resuscitator dead space.

Applicable Standards

Performance Testing Standards

Standards No.	Standards Organization	Standards Title	Version	Date
10651-5	ISO	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators	1st Ed.	2006
10651-4	ISO	Lung ventilators – Part 4: Particular requirements for operator powered resuscitators	1st Ed.	2002
5356-1	ISO	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	4th Ed.	2004
5367	ISO	Anaesthetic and respiratory equipment - breathing sets and connectors	5th Ed.	2014
14971	ISO	Medical Devices - Application of risk management to medical devices	2nd Ed.	2007
13544-2	BS EN	Respiratory therapy equipment - Part 2: Tubing and connectors	2002+A1	2009

Biocompatibility Standards

Standards No.	Standards Organization	Standards Title	Version	Date
10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	3rd Ed.	2009

10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	3rd Ed.	2010
10993-17	ISO	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances	1st Ed.	2002
10993-18	ISO	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials	1st Ed.	2005
18562-1	ISO	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process	1st Ed.	2017
18562-2	ISO	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter	1st Ed.	2017
18562-3	ISO	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 3: Tests for emissions of volatile organic compounds (VOCs)	1st Ed.	2017
18562-4	ISO	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 4: Tests for leachables in condensate	1st Ed.	2017

Bench Performance Testing

The subject and predicate devices were both subjected to the same standards. The subject device met all quantitative and qualitative requirements, as published in the applicable standards. The specifications in the *Substantial Equivalency Comparison Table* demonstrate that the function and performance are the same or similar between the subject and predicate devices.

The subject device passed the following performance requirements per the applicable performance standards cited above:

- Delivered Oxygen Concentration
- Resistance to Spontaneous Breathing – Inspiratory Resistance
- Resistance to Spontaneous Breathing – Gas Input Pressure
- Resistance to Spontaneous Breathing – Expiratory Resistance
- Inadvertent PEEP

- Delivered Volume
- Pressure Limitation
- Operation of Manual Trigger
- Patient Valve Function after Contamination with Vomitus
- Function after Storage Conditions
- Function During Operating Conditions after Storage Conditions
- Function after Drop Test
- Function after Immersion in Water
- Inspection of Surfaces, Corners, and Edges
- Size Limitation
- Resuscitation Mass
- Patient Valve with Patient Connection Port Mass
- Function after Dismantling and Reassembly
- Legibility and Durability of Markings
- Flow-Direction-Sensitive Component
- Pressure Limit Under Single Fault Condition
- Resuscitator Dead Space
- Inadvertent Continuing Expiratory Pressure
- Indication of Use of Function Affecting Performance
- Indication of Pneumatic Power Rating
- Durability of Markings
- Identification
- Controls and Indicators
- Indication of Pressure Limiting Device Setting
- Pressure-Limitation Activation Alarm Signal

The below performance requirements in the standards require actual values to be stated on instructions for use and does not define acceptance criteria:

- Manometer Accuracy Reading
- PEEP Flow Range
- Gas Container Capacity
- Protection Against Accidental Adjustments

Substantial Equivalence Conclusion

SafeT T-Piece Resuscitator has the same intended use, indications for use, and physical attributes as Mercury Medical Neo-Tee T-Piece Resuscitator. Any minor differences in the materials used to make the subject device when compared to the predicate device have been successfully evaluated by SunMed through extensive performance and biocompatibility testing on their device, such that the information submitted to the FDA demonstrates that the subject device is as

safe and effective as the predicate device and does not raise any new questions of safety and effectiveness. SafeT T-Piece Resuscitator, as designed and manufactured by SunMed, has been determined to be substantially equivalent to Mercury Medical Neo-Tee T-Piece Resuscitator.