May 11, 2018

Foremount Enterprise Co., Ltd.
% Paul Dryden
President
ProMedic LLC.
131 Bay point Dr, NE
St. Petersburg, Fl 33704

Re: K170663
Trade/Device Name: Foremount Disposable PVC Resuscitator Model A1, A2, B1, B2 and Accessories
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual emergency ventilator
Regulatory Class: Class II
Product Code: BTM
Dated: April 6, 2018
Received: April 9, 2018

Dear Paul 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Geeta K. Pamidimukkala -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)*

K170663

Device Name

Foremount Disposable PVC Resuscitator Model A1, A2, B1, B2 and Accessories

Indications for Use *(Describe)*

Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:
Infant: less than or equal to 10Kg, Child: less than or equal to 23 Kg, Adult: greater than 23 Kg

This manual resuscitator may be supplied with a single patient use positive end expiratory pressure (PEEP) valve and / or disposable Airway Pressure Manometer.

The PEEP Valve is a single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions. Intended for patients that the clinician has determined need PEEP.

The Disposable Manometer is a single patient use manometer intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is being submitted by Foremount Enterprise in accordance with 21 CFR 807.92.

Date: May 8, 2018

Submitter

Submitter's name: Foremount Enterprise Co., Ltd.

Submitter's address: No. 17, Alley 15, Lane 5, Shenan Street, Shengang Dist., Taichung City 429, Taiwan

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Name of the Device(s) and Predicate(s)

Trade Name: Foremount Disposable PVC Resuscitator Model A1, A2, B1, B2 and Accessories
Device Name: Ventilator, Emergency, Manual (Resuscitator)
Product Code: BTM
Regulation #: 868.5915
Device Class: 2

Predicate: K082092 – GaleMed Dispo-Bag Manual Resuscitator and accessories including Ventilation Bag, Patient Valve, Intake Valves, Reservoir Bag, Oxygen Tubing, Cushion Mask and PEEP Valve

Disposable Manometer

Predicate: K122077 - Intersurgical – Airway Pressure Manometer

Device Description:

Foremount Disposable PVC Resuscitator Model A1, A2, B1, B2 and Accessories
Foremount Disposable PVC Resuscitators are portable medical devices used to temporarily augment ventilation in patients during ventilatory insufficiency or ventilatory failure. They consist of Ventilation Bag, Patient Valve, Intake Valves, Reservoir Bag, Oxygen Tubing, Cushion Mask, and optional Diverter Ring, PEEP Valve and Manometer. Foremount Disposable PVC Resuscitators come in three sizes along with a ventilation bag:

- Infant - Less than or equal to 10 kg
- Child - less than or equal to 23 kg
- Adult - Greater than 23 kg.

The ventilation bags are available in three sizes based upon the intended patient population. They are provided with masks in three sizes (#1 - Infant, #3 - Child, and #5 - Adult). The patient valve includes a duck-bill valve to prevent rebreathing and incorporates a 40 cmH_2O pop off valve for Child and Infant models. The patient valve includes a duck-bill valve to prevent rebreathing and incorporates a 60 cmH_2O pop off valve for Adult models.

Indications for Use:
Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:

Infant: less than or equal to 10Kg, Child: less than or equal to 23 Kg, Adult: greater than 23 Kg

This manual resuscitator may be supplied with a single patient use positive end expiratory pressure (PEEP) valve and / or disposable Airway Pressure Manometer.

The PEEP Valve is a single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions. Intended for patients that the clinician has determined need PEEP.

The Disposable Manometer is a single patient use manometer intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems.

Substantially Equivalent Information (Predicate Device)
Foremount devices are equivalent to the following predicate devices:

Table 1 outlines the predicate selection for each.

Description	**Foremount**	**Predicate**
Disposable resuscitator	Without Pop-off valve	GaleMed – K082092
	With Pop-off valve	
	With Manometer and PEEP valve	
	With or without face mask and oxygen collection bag	
PEEP valve		
Pressure manometer	Intended to monitor airway pressure	Intersurgical – K122077 Note other resuscitators have been cleared with the ability to add a manometer.

Table 1 – Predicate Selection

Comparison to Predicate Devices
Discussion of Substantial Equivalence for the Resuscitator

Table 2 – Comparison Disposable Resuscitator Devices

	Subject Device				**Predicate / K082092**
	Models A1 Adult, Child, and Infant	**Model A2 Adult**	**Models B1 Adult, Child, and Infant**	**Model B2 Adult**	**GaleMed Dispo-Bag Manual Resuscitator**
Classification	BTM CFR 868.5915 Ventilator, Emergency, Manual (Resuscitator)				BTM CFR 868.5915 Ventilator, Emergency, Manual (Resuscitator)
Indications for Use	Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:	Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:	Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:	Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:	Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:
Population	Infant ≤ 10Kg Child ≤ 23 Kg Adult > 23 Kg	Adult > 23 Kg	Infant ≤ 10Kg Child ≤ 23 Kg Adult > 23 Kg	Adult > 23 Kg	Infant ≤ 10Kg Child ≤ 23 Kg Adult > 23 Kg
Environment of Use	hospital, transport, emergency, and post hospital care				hospital, transport, emergency, and post hospital care
Contraindications	Infant > 10kg Child > 23 kg Adult < 23 kg	Adult < 23 kg	Infant > 10kg Child > 23 kg Adult < 23 kg	Adult < 23 kg	Infant > 10kg Child > 23kg Adult < 23 kg
Components	Self-inflating bag Intake valves Oxygen collection bag Oxygen tubing Patient connector Face mask Options - Pop-off, PEEP valve, Pressure manometer				Self-inflating bag Intake valves Oxygen collection bag Oxygen tubing Patient connector Face mask Options - Pop-off, PEEP valve

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	Subject Device				**Predicate / K082092**
	Models A1 Adult, Child, And Infant	**Model A2 Adult**	**Models B1 Adult, Child, and Infant**	**Model B2 Adult**	**GaleMed Dispo-Bag Manual Resuscitator**
Principle of operation	The patient valve contains a duckbill valve that directs air from compression of the ventilation bag through a patient connector into the patient airway during inspiration and directs the patient expired air out to the atmosphere when the ventilation bag is released during exhalation. If the patient valve incorporates a pop off valve (40 cmH_2O for infant and child and 60 cmH_2O for adult), excessive pressure will be exhausted to atmosphere to prevent pressure trauma.				Similar
Specifications					
Duration of use	Single patient, disposable <24 hours				Single patient, disposable <24 hours
Operational temperature	-18ºC ~50ºC				-18ºC ~50ºC
Storage temperature	-40ºC ~60ºC				-40ºC ~60ºC
Dimensions	Adult: 445x190 mm Child: 350x177 mm Infant: 325x165 mm	Adult: 445x190 mm	Adult: 445x190 mm Child: 350x177 mm Infant: 325x165 mm	Adult: 445x190 mm	Adult: 570x190 mm Child: 510x190 mm Infant: 430x180 mm
Intake valves	External 2 valve design Integrated design				2 valves All in one design
Can provide supplemental oxygen	Yes				Yes
Ventilation Bag Volume	Adult 1700 ml Child 500 ml Infant 320 ml	Adult 1700 ml	Adult 1700 ml Child 500 ml Infant 320 ml	Adult 1700 ml	Adult 1500 ml Child 600ml Infant 280 ml
Oxygen collection Bag Volume	Adult 1000 ml Child 1000 ml Infant 600 ml	Adult 1000 ml	Adult 1000 ml Child 1000 ml Infant 600 ml	Adult 1000 ml	Adult 1000 ml Child 1000 ml Infant 500 ml
Max Stroke Volume (single hand)	Adult 650 ml Child 370 ml Infant 180 ml	Adult 650 ml	Adult 650 ml Child 370 ml Infant 180 ml	Adult 650 ml	Adult 700 ml Child 360 ml Infant 150 ml
Dead Space	~ 3.8 ml for all sizes				4.5 ml for all sizes as tested 6.8 ml from labeling
					Note: All values of the predicate were measured values

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	Subject Device				**Predicate / K082092**
	Models A1 Adult, Child, and Infant	**Model A2 Adult**	**Models B1 Adult, Child, and Infant**	**Model B2 Adult**	**GaleMed Dispo-Bag Manual Resuscitator**
Inspiratory Resistance Maximum Infant@5lpm Child@5lpm Adult@50lpm	Infant - 0.5cm H_2O Child - 0.5cm H_2O Adult - 3cm H_2O				Infant - 0.5cm H_2O Child - 0.7cm H_2O Adult – 3.3cm H_2O
Expiratory Resistance Maximum Adult@50 lpm Child & Infant@5 lpm	Infant - 0.5cm H_2O Child - 0.5cm H_2O Adult – 2.8 cmH_2O				Infant -0.8cm H_2O Child - 0.8cm H_2O Adult – 2.6 cmH_2O
Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)	**Infant** Vt – 70 ml x 20 bpm Vt – 70 ml x 30 bpm	**2 lpm** 90% 87%	**5 lpm** 98% 99%	**10 lpm** 98% 98%	**2/5/10 lpm** 91/97/99% 87/96/98%
Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)	**Child** Vt – 200 ml x 20 bpm Vt – 300 ml x 30 bpm	**2 lpm** 57% 39%	**5 lpm** 99% 66%	**10 lpm** 98% 98%	**2/5/10 lpm** 56/99/99% 42/63/99%
Supplemental Oxygen% at different flow rates and Tidal Volumes (VT)	**Adult** Vt – 600 ml x 12 bpm Vt – 750 ml x 12 bpm Vt – 1000 ml x 20 bpm	**5 lpm** 83% 57% 40%	**10 lpm** 99% 99% 60%	**15 lpm** 99% 99% 70%	**5/10/15 lpm** 84/98/99% 76/98/99% 40/61/71%
Pop-Off or Pressure Limiting	40 cm H_2O 60 cm H_2O				40 cm H_2O 60 cm H_2O
Ability to add PEEP valves	Yes 0-20 cm H_2O				Yes 0-20 cm H_2O
Patient connectors	15 / 22 mm				15 / 22 mm
PEEP valve fittings	22 / 30 mm				22 / 30 mm
Face mask	#1 – Infant #2 – Child #3 – Adult	#3 – Adult	#1 – Infant #2 – Child #3 – Adult	#3 – Adult	#1 – Infant #2 – Child #3 – Adult
					Note: All values of the predicate were measured values

	Subject Device				**Predicate / K082092**
	Models A1 Adult, Child, and Infant	**Model A2 Adult**	**Models B1 Adult, Child, and Infant**	**Model B2 Adult**	**GaleMed Dispo-Bag Manual Resuscitator**
Pressure manometer Optional	0-60 cm H_2O				0-60 cm H_2O Reference Intersurgical K122077
Biocompatibility	Externally communicating, tissue and Surface Contact, skin Limited duration of use (<24 hours) Testing – Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Gas emission VOC, $PM_{2.5}$, Inorganic gases (Ozone, CO, CO_2)				Same patient exposure and duration
Materials	PVC, Polycarbonate, Silicone				Same
ISO 5356-1	Conical connectors				Same
ISO 10651-4	Lung ventilators – operator powered				Same
Shelf-life	5 years				3 years

Discussion of Substantial Equivalence and Differences for the Resuscitator

The Foremount Disposable Resuscitators are viewed as substantially equivalent to the predicate device because:

Indications for Use –
The proposed indications for use are similar to the predicate. There are no differences in the Indications for use.

Patient Population –
The patient population is similar to the predicate. There is no difference in the population compared to the predicate.

Environment of Use –
The proposed environments of use are similar to the predicate. There are no differences in the environment of use.

Technology –
The design and principle of operation is similar to the predicate. The configuration and functionality is similar. The differences in specification, e.g. maximum stroke volume and ventilation bag volume do not raise new safety or effectiveness concerns related to substantial equivalence as ISO 10651-4 specifies the minimum requirements and the subject device and the predicate both meet the minimum requirements as listed in the standard.

Substantial Equivalence for the PEEP Valves

The subject device includes the use of PEEP Valves as part of the optional accessories.

Table 3 provides a detailed comparison of the subject PEEP valves to the predicate PEEP valves which are part of the predicate K082092 GaleMed.

Table 3 – Substantial Equivalence for PEEP Valves

	Subject PEEP Valve	**Predicate GaleMed – K082092**
Classification	BYE CFR 868.5965 Attachment, Breathing, Positive End Expiratory Pressure	BYE CFR 868.5965 Attachment, Breathing, Positive End Expiratory Pressure
Indications for Use	Single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.	Single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.
Patient Population	Intended for patients that the clinician has determined need PEEP.	Not specified
Environment of Use	Hospital, transport, emergency, and post hospital care	Hospital, transport, emergency, and post hospital care
Contraindications	Contraindicated in a patient who does not require elevated end expiratory pressure therapy.	Contraindicated in a patient who does not require elevated end expiratory pressure therapy.
Principle of Operation	Exhaling exerts pressure on a spring which has tension that is calibrated to a range of pressures. Adjustment of the spring tension changes the PEEP pressure.	Exhaling exerts pressure on a spring which has tension that is calibrated to a range of pressures. Adjustment of the spring tension changes the PEEP pressure.
Pressure range	0 to 10 cmH_2O 5 to 20 cmH_2O	2.5 to 10 cmH_2O 5 to 20 cmH_2O
Adjustable	Yes	Yes and fixed

Accuracy	+/- 2 cmH_2O	+/- 2 cmH_2O
Connectors	22 mm / 30 mm	22 mm / 30 mm
Biocompatibility	Externally communicating, tissue Limited duration of use (<24 hours)	Same
Materials	Polycarbonate, Silicone, Stainless Steel spring	Same
Performance Testing	Accuracy Repeatability Effects of Aging Drop Test Conical fittings	

Discussion of Substantial Equivalence and Differences for the PEEP Valves

The Disposable PEEP Valves are viewed as substantially equivalent to the predicate device because:

Indications for Use –

The proposed indications for use are similar to the predicate. There is no difference in the indications for use compared to the predicate.

Patient Population –

There is no specific patient population for PEEP valves. There is no difference in the population compared to the predicate.

Environment of Use –

The proposed environments of use are similar to the predicate. There is no difference in the environment of use compared to the predicate.

Technology –

The design and principle of operation is similar to the predicate. There is no difference in the technology, design or principle of operation compared to the predicate

Substantial Equivalence for the Manometer

The subject device includes the use of a disposable pressure manometer as part of the optional accessories.

Table 4 provides a detailed comparison of the subject Manometer to the predicate which is the Intersurgical K122077.

Table 4 – Substantial Equivalence for Manometer

	Subject **Manometer**	**Predicate** **Intersurgical – K122077**
Classification	CAP CFR 868.2600 Monitor, Airway Pressure	CAP CFR 868.2600 Monitor, Airway Pressure
Indications for Use	The Disposable Manometer is a single patient use manometer is intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems.	The Disposable Manometer is a single patient use manometer is intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems.
Patient Population	Intended for use with a resuscitator	Intended for use with a resuscitator
Environment of Use	Hospital, transport, emergency, and post hospital care	Hospital, transport, emergency, and post hospital care
Principle of Operation	The technology is the use of a calibrated spring that when pressure rises the springs is compressed raising an indicator and showing the pressure via markings on the manometer cylinder has calibrated marking at 10 cmH_2O intervals between 0 through 60 cmH_2O.	Same
Pressure range	0 to 60 cmH_2O	0 to 60 cmH_2O
Markings	Increments of 10 cmH_2O	Increments of 10 cmH_2O
Accuracy	±1 cmH_2O @ 0-10 cmH_2O ±2 cmH_2O @ 20-30 cmH_2O ±3 cmH_2O @ 40-60 cmH_2O	±2 cmH_2O @ 0-10 cmH_2O ±4 cmH_2O @ 20 cmH_2O ±5 cmH_2O @ 30-40 cmH_2O ±7 cmH_2O @ 50-60 cmH_2O
Connectors	15 / 22 mm	15 / 22 mm
Biocompatibility	Externally communicating, tissue Limited duration of use (<24 hours)	Same
Materials	Polycarbonate, Silicone, Stainless Steel Springs	Same

Performance Testing	Accuracy Repeatability Effects of Aging Drop Test Conical fittings	

Discussion of Substantial Equivalence and Differences for the Manometer

The Disposable Pressure Manometer is viewed as substantially equivalent to the predicate device because:

Indications for Use –

The proposed indications for use are similar to the predicate. There is no difference in the indications for use compared to the predicate.

Patient Population –

There is no specific patient population for Manometers. There is no difference in the population compared to the predicate.

Environment of Use –

The proposed environments of use are similar to the predicate. There is no difference in the environment of use compared to the predicate.

Technology –

The design and principle of operation is similar to the predicate. There is no difference in the technology, design or principle of operation compared to the predicate.

Summary of Performance – Non-clinical for All Devices

The following tests and standards were considered in determining the safety and performance of the subject devices as compared to the predicates.

Biocompatibility of Patient Contacting Materials –

The materials of the Resuscitator bag, PEEP valve, manometer, and face mask have the following patient contact:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – limited (<24 hours)

The face mask are also

- Surface Contact
- Intact skin
- Duration of Use – limited (<24 hours)

Discussion -

We performed the applicable tests to support biocompatibility. These tests included:

- Cytotoxicity – ISO 10993-5 (2009) - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization and Irritation – ISO 10993-10 (2010) - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Acute Systemic Toxicity – ISO 10993-11 (2010) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Gas Emission VOC testing
- $PM_{2.5}$ - ISO 18562-2:2017 – Biocompatibility Evaluation of Breathing Gas Pathways – Part 2: Tests for Emissions of Particulate Matter
- Inorganic gases – CO, CO_2, and Ozone

The materials were found to be non-cytotoxic, non-sensitizers, and non-irritants.

Bench Testing

Applicable standards for bench testing:

- ISO 10651-4:2002 - Lung ventilators Part 4: Particular requirements for operator-powered resuscitators.
- ISO 5356-1:2004 - Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.

Tests performed included:

- Storage condition performance
- Operating condition performance
    - Delivered stroke volume
    - Supplementary oxygen delivered concentration at different Tidal Volumes
    - Measurement of Inspiratory and Expiratory Resistance
    - Patient Valve malfunction
    - Pressure limits of Pop-off
    - Dead space
- Function after Contamination with Vomitus
- Drop Test
- Immersion in Water
- Evaluation and testing of conical fittings

- Effects of aging pre- and post-conditioning performance
- Accuracy and Repeatability

Discussion of Differences and Substantial Equivalence Conclusion

There are no differences between the proposed device and the predicates which raise different safety or effectiveness concerns. We can conclude that the proposed device and accessory components can be considered substantially equivalent. Based upon the testing the sponsor has demonstrated the equivalence of the subject device compared to the predicate.