February 14, 2020

Hill-Rom Services Pte Ltd
Paul Dryden
Consultant for Hill-Rom
1 Yishun Ave 7
Singapore, Sg 768923

Re: K192143
Trade/Device Name: Maximus™ System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: January 20, 2020
Received: January 21, 2020

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Division Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: January 30, 2020
See PRA Statement below.

510(k) Number *(if known)*

K192143

Device Name

Maximus™ System

Indications for Use *(Describe)*

The Maximus™ System provides features of both the Synclara™ System and the Volara™ System.

The **Maximus™ System, when used as a Synclara™ Cough System** is intended for use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow or respiratory muscle weakness.

The **Maximus™ System, when used as a Volara™ System** is intended for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.

Patient Population
The Maximus™ System, when used as a Synclara™ Cough System, is intended to deliver therapy to the population of pediatric to adult patients in both acute and home care settings.

The Maximus™ System, when used as a Volara™ System, is intended to deliver therapy to adults and children over the age of 2 in the acute care setting.

The Maximus™ System, when used as a Volara™ System, is intended to deliver therapy to adults and children over the age of 5 in the home care setting.

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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Date Prepared 14-Feb-20

Submission Sponsor:
Hill-Rom Services Pte Ltd
1 Yishun Ave 7 Tel – 011 - 65 6499 7391
Singapore, 768923, Singapore Fax – 011 - 65 65945201

Official Contact: Alvin Tan – R&D Executive Director

Proprietary or Trade Name: Maximus™ System

Common/Usual Name: Noncontinuous ventilator (IPPB)

Classification Code/Name: NHJ – non-continuous ventilator (IPPB)
21 CFR 868.5905, Class II

Predicate Devices: K124032 – Hill-Rom MetaNeb®
K151689 – Hill-Rom MetaNeb®
K132988 – Vital Cough

Reference Devices: K121955 - Philips Respironics Cough Assist T70
K895485 – Bird IPV

Device Description:
The Maximus™ System is a 2 in 1 device which is a combination of two (2) already cleared devices. The Maximus™ System provides the individual therapies of the predicates: Vital Cough and MetaNeb®. The Maximus™ can be programmed to allow the user to provide both therapies or one only. The 2 main types of therapies are referred to as:

- MIE (Mechanical Insufflation-Exsufflation)
- OLE (Oscillation and Lung Expansion)

The Maximus™ system and the relevant predicates are presented in **Tables 1** to **3.**

Indications for Use:
The Maximus™ System provides features of both the Synclara™ System and the Volara™ System.

The **Maximus™ System, when used as a Synclara™ Cough System** is intended for use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow or respiratory muscle weakness.

The **Maximus™ System, when used as a Volara™ System** is intended for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.

Patient Population
The Maximus™ System, when used as a Synclara™ Cough System, is intended to deliver therapy to the population of pediatric to adult patients in both acute and home care settings.
The Maximus™ System, when used as a Volara™ System, is intended to deliver therapy to adults and children over the age of 2 in the acute care setting.
The Maximus™ System, when used as a Volara™ System, is intended to deliver therapy to adults and children over the age of 5 in the home care setting.

Table 1 – Maximus™ Substantial Equivalence Table

	Proposed Maximus™	**Predicate MetaNeb®**	**Predicate Vital Cough with Flutter**
510(k)	TBD	K124032 and K151689	K132958
CFR Classification	868.5905 NHJ	868.5905 NHJ	868.5905 NHJ
Classification name	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)
Intended Use	Indicated to help with clearing secretions Indicated for mobilization of secretions lung expansion therapy treatment and prevention of pulmonary atelectasis ability to provide supplemental oxygen when used with compressed oxygen.	Indicated for mobilization of secretions lung expansion therapy treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.	Indicated to help with clearing secretions
Indications for Use	The **Maximus™** System, Model POPT1 provides features of both the Synclara™ System and the Volara™ System. The Maximus™ System, when used as a **Synclara™** Cough System is intended for use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow or respiratory muscle weakness. The Maximus™ System, Model POPT1, when used as a **Volara™** System is intended for the mobilization of secretions, lung	The MetaNeb® System is indicated for mobilization of secretions, lung	The Vital Cough is intended for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flaw resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask. mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate

	expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.	expansion therapy, the treatment and prevention of pulmonary atelectasis, and can provide supplemental oxygen when used with compressed oxygen.	training. For use on adult or pediatric patients.
Environments of Use	Hospital sub-acute facilities Nursing care Homecare	Hospital sub-acute facilities Nursing care Homecare (K151689)	Hospital sub-acute facilities Nursing care Homecare
Patient Population	**Volara™ mode:** Adult, Child > 2 years old (acute) >5 year (home care) **Synclara™ mode:** Adult and pediatric	Adult, Child > 2 years old (acute) >5 years old (home care)	Adult and pediatric (Age not designated)
Therapy Modes	**Volara™ therapy modes:** CPEP, CHFO, Aerosol **Synclara™ therapy modes:** Inhale, Exhale, PAP	CPEP, CHFO, Aerosol	Inhale, Exhale, PAP
Pulse Oximeter Option	Can connect via Bluetooth to Beijing Choice Electronic Technology Co., Ltd. Fingertip Pulse Oximeter, K142888. Only displays the heart rate and SpO_2 data.	Not offered	Not offered
Volara™ features			
Continuous Positive Expiratory Pressure (CPEP)	Controlled static flow with positive pressures < 30 cmH_2O	Controlled static flow with positive pressures < 30 cmH_2O	Device does not offer this feature.
Continuous High Frequency Oscillations (CHFO)	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures, ≤ 70 cmH_2O+	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures, ≤ 30 cmH_2O	Device does not offer this feature.
Aerosol	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only via mouthpiece and face mask. Aerosol may not be delivered when the in-line ventilator adapter is used	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only via mouthpiece, face mask or in-line ventilator adapter.	Device does not offer this feature.

	Proposed Maximus™	Predicate MetaNeb®	Predicate Vital Cough with Flutter
Synclara™ features			
Maximum Positive Pressure	70 cmH_2O*	Device does not offer this feature.	50 cmH_2O
Maximum Negative Pressure	-70 cmH_2O*	Device does not offer this feature.	-50 cmH_2O
Inhalation, Exhalation and PAP duration	0 to 5 seconds	Device does not offer this feature.	0 to 5 seconds
Flutter frequency	1 – 20 Hz	Device does not offer this feature.	0 – 20 Hz
Accessories			
Patient Circuit configurations	**Volara™ Patient Circuit:** Disposable circuit referred to as "handset" includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller. **Synclara™ Patient Circuit:** Disposable single patient use circuit consisting of Bacterial/Viral filter, hose, mouthpiece and facemask adapter.	Disposable circuit referred to as "handset" includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller.	Disposable single patient use circuit consisting of Bacterial/Viral filter, hose, mouthpiece and facemask adapter.
Patient circuit settings	No resistance adjustment feature on patient circuit. Therapy settings are all done at the control unit.	Expiratory resistance Adjustment	No resistance adjustment feature on patient circuit. Therapy settings are all done at the control unit.

***** Use of Reference Philips Respironics Cough Assist T70 (K121955)
+ Use of Reference Bird IPV (K895485) for this pressure

	Proposed Maximus™	Predicate MetaNeb®	Predicate Vital Cough with Flutter
Patient Interface	**Acute care:** Mouthpiece Face mask Insert into ventilator Adapter to a patient's endotracheal tube or tracheostomy tube. **Home care:** Mouthpiece Face mask Insert into ventilator Adapter to a patient's endotracheal tube or tracheostomy tube.	**Acute care:** Mouthpiece Face mask Insert into ventilator Adapter to a patient's endotracheal tube or tracheostomy tube. **Home care:** Mouthpiece Face mask Insert into ventilator Adapter to a patient's endotracheal tube or tracheostomy tube.	Mouthpiece Face mask Adapter to a patient's endotracheal tube or tracheostomy tube.
Controller			
Principle of operation	Electro-Mechanical device Air or oxygen	Pneumatic Air or oxygen	Pneumatic Air or oxygen
Setting Options	On/Off Frequency selection for CHFO mode (Touch Screen Control) Pressure adjustment for CHFO mode (Touch Screen Control) Pressure adjustment for CPEP mode (Touch Screen Control) Pressure manometer Pressure adjustment for Inhale, Exhale, PAP mode (Touch Screen Control) Flow adjustment for Inhale mode. (Touch Screen Control) Frequency adjustment for Flutter feature. (Touch Screen Control) Pressure adjustment for flutter feature. (Touch Screen Control)	On/off Frequency selection for CHFO mode (control knob) - Pressure adjustment for CPEP mode (control knob) Pressure manometer - - -	On/Off - - - Pressure manometer Pressure adjustment for Inhale, Exhale, PAP mode (Touch Screen Control) Flow adjustment for Inhale mode. (Touch Screen Control) Frequency adjustment for Flutter feature. (Touch Screen Control)

Table 2 – Substantial Equivalence of Volara™ Oscillation and Lung Expansion Therapy

	Proposed Volara™	Primary Predicate MetaNeb®	Secondary Predicate MetaNeb® 4 System
510(k) Number	-	K124032	K151689
CFR classification	Regulation Number: 868.5905 Product code: NHJ		
Indications for Use (Brief)	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with oxygen.	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with compressed oxygen.
Environment of Use	Hospital Sub-acute facilities Nursing care Homecare	Hospital Sub-acute facilities	Hospital Sub-acute facilities Nursing care Homecare
Patient Population	**Acute care** Adult Child > 2 years old **Home care** 5 years old and above whom can follow verbal instructions	**Acute care** Adult Child > 2 years old	**Home care** 5 years old and above whom can follow verbal instructions
Modes	CPEP, CHFO, Aerosol	CPEP, CHFO, Aerosol	CPEP, CHFO, Aerosol
Continuous Positive Expiratory Pressure (CPEP)	Controlled static flow with positive pressures < 30 cmH_2O	Controlled static flow with positive pressures < 30 cmH_2O	Controlled static flow with positive pressures < 30 cmH_2O
Continuous High Frequency Oscillations (CHFO)	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 70 cmH_2O*	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH_2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressures ≤ 30 cmH_2O
Aerosol Only	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only via mouthpiece and face mask. Aerosol may not be delivered when the in-line ventilator adapter is used.	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only via mouthpiece, face mask or in-line ventilator adapter.	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only.

	Proposed Volara™	Primary Predicate MetaNeb®	Secondary Predicate MetaNeb® 4 System
* Use of Reference Bird IPV (K895485) for this pressure			
Patient Circuit	Disposable circuit referred to as "handset" includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller.	Disposable circuit referred to as "handset" includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller.	Disposable circuit referred to as "handset" includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller. No in-line filter (Home) In-line filter (Acute care)
Patient Circuit Settings	No resistance adjustment feature on patient circuit. Adjustments all done at the control unit.	Expiratory resistance adjustment	Expiratory resistance adjustment
Patient Interface	**Acute care** Mouthpiece Face mask Insert into ventilator circuit **Home care** Mouthpiece Face mask	**Acute** Mouthpiece Face mask Insert into ventilator circuit	**Home** Mouthpiece Face mask
Controller	Electro-Mechanical device and air	Pneumatic and air or oxygen	Pneumatic and air or oxygen
Controller settings	On/Off Frequency selection for CHFO mode (Touch Screen Control) Pressure adjustment for CHFO mode (Touch Screen Control) Pressure adjustment for CPEP mode (Touch Screen Control) Pressure manometer	On/off Frequency selection for CHFO mode (control knob) - Pressure adjustment for CPEP mode (control knob) Pressure manometer	On/off Frequency selection for CHFO mode (control knob) - Pressure adjustment for CPEP mode (control knob) Pressure manometer
Ventilator connection	Placed in-line in the inspiratory limb of the ventilator circuit with a standard "T" adapter. Only for acute care environment	Placed in-line in the inspiratory limb of the ventilator circuit with a standard "T" adapter. Only for acute care environment	Placed in-line in the inspiratory limb of the ventilator circuit with a standard "T" adapter. Only for acute care environment

Table 3 – Substantial Equivalence Comparison – Synclara™ - MIE Therapy

	Proposed Synclara™	Primary Predicate device Vital Cough with Flutter	Secondary Predicate device Vital Cough
510(k) Number	-	K132988	K120277
CFR classification	Regulation Number: 868.5905 Product code: NHJ		
Indications for Use	For use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow or respiratory muscle weakness.	For use on any patient unable to cough or clear secretions effectively due to reduced peak cough resulting from high. spinal cord injuries, neuromuscular deficits clearance and lung or severe fatigue or severe fatigue associated with intrinsic lung disease.	For use on any patient unable to cough or clear secretions effectively due to reduced peak cough resulting from high. spinal cord injuries, neuromuscular deficits clearance and lung or severe fatigue or severe fatigue associated with intrinsic lung disease.
Environment of Use	Home, hospital/Institution	Home, hospital/Institution	Home, hospital/Institution
Patient Population	Adult and pediatric	Adult and pediatric	Adult and pediatric
Modes	Inhale, Exhale, PAP	Inhale, Exhale, PAP	Inhale, Exhale, PAP
Maximum Positive Pressure	70 cmH_2O* Maximum pre-set is 50 cmH_2O in home setting	50 cmH_2O	50 cmH_2O
Maximum Negative Pressure	-70 cmH_2O*	-50 cmH_2O	-50 cmH_2O
Inhalation, Exhalation and PAP duration	0 to 5 seconds	0 to 5 seconds	0 to 5 seconds
Flutter Frequency	1 – 20 Hz	0 – 20 Hz	No Flutter
Patient Circuit	Disposable single patient use circuit consisting of Bacterial/Viral filter, hose, mouthpiece and facemask adapter.	Disposable single patient use circuit consisting of Bacterial/Viral filter, hose, mouthpiece and facemask adapter.	Disposable single patient use circuit consisting of Bacterial/Viral filter, hose, mouthpiece and facemask adapter.
Patient Interface	facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.	facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.	facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.
* Use of Reference Philips Respironics Cough Assist T70 (K121955)			

	Proposed Synclara™	Primary Predicate device Vital Cough with Flutter	Secondary Predicate device Vital Cough
Controller settings	On/Off Pressure adjustment for Inhale, Exhale, PAP mode (Touch Screen Control) Flow adjustment for Inhale mode. (Touch Screen Control) Frequency adjustment for Flutter feature. (Touch Screen Control) Pressure adjustment for flutter feature. (Touch Screen Control) Pressure manometer	On/Off Pressure adjustment for Inhale, Exhale, PAP mode (Touch Screen Control) Flow adjustment for Inhale mode. (Touch Screen Control) Frequency adjustment for Flutter feature. (Touch Screen Control) - Pressure manometer	On/Off Pressure adjustment for Inhale, Exhale, PAP mode (Touch Screen Control) Flow adjustment for Inhale mode. (Touch Screen Control) - - Pressure manometer

Substantial Equivalence Discussion

The Maximus™ system is viewed as substantially equivalent to the predicate devices because:

Indications – The proposed indications for use for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with compressed oxygen are identical to the predicates.
Discussion: The indications for use are identical to the predicates Hill-Rom MetaNeb® system (K124032) and Vital Cough (K132988). The subject device is a new design of these technologies. We have expanded the use of the patient interface to include a face mask in the home setting.

Patient Population – The patient populations are identical to the predicates.
Discussion: We have not changed the patient populations vs. the predicates.

Environment of Use – The environments of use identical to the predicates.
Discussion: We have not changed the use environments.

Technology – The Maximus™ is a redesign of the combination of the MetaNeb® system and the Vital Cough system into a single unit. The software-controlled Maximus™ replaces the manual control systems. Functionally the performance and therapy mode functions and performance are identical to the respective predicates.

We have added changes to some of the pressure limits based upon reference devices with similar indications for use and clinician input.

The Maximus™ can connect to a cleared pulse oximeter via BLE and can display only the heart rate and SpO_2 for the convenience of the user. Connects to K142888. The predicates do not have the feature.

Discussion: The design of Maximus™ is different from the predicates in that it allows for software control of settings and the user interface is a GUI screen. We have evaluated the performance and usability with different user types.

Performance – The basic performance features and parameters are identical to the predicates. We have proposed some changes listed below with their respective rationale.

Rationale and Support of Product Differences / Modifications

OLE
Higher Peak Positive Pressures

We have found that clinicians want to provide a higher Positive Peak Pressure up to 70 cm H_2O vs. the original 30 cmH_2O. The reference device Bird IPV (K895485) has similar indications for use and patient population and provides peak expiratory pressures up to 80 cm H_2O.

Patient Circuit – Adjustable Resistance
The predicate patient circuit has a selector ring which could be adjusted manually. The proposed change in Maximus™ with the touch screen is that controls would be performed on-screen.

MIE
Higher Maximum Positive and Negative Pressures

We have found that clinicians want to be able to provide a wider range of Maximum Positive and Negative pressures during couch assist. We are proposing to increase the range from $\pm$50 cm H_2O to $\pm$70 cm H_2O. The reference Philips Respironics Cough Assist T70 (K121955) has the same indications for use and population that provides pressures of $\pm$70 cm H_2O.

Nebulizer Performance
The comparative nebulizer performance across all therapy modes and range of pressures demonstrated that the Maximus performance with the Philips SideStream nebulizer was substantially equivalent to the predicate. In addition, testing demonstrated that the performance with a mouthpiece vs. a face mask were equivalent. Aerosol may not be delivered when the in-line ventilator adapter is used.

Manual Mode
The Manual Mode is restricted to highly trained home users via “pass key”.

Discussion of Differences
The differences presented above have not raised new or different questions of safety or effectiveness from the predicates or the reference devices cited.

Non-clinical Comparative Performance

Biocompatibility of Patient Contacting Materials – The materials in the gas and fluid pathway are considered as having 2 types of patient contact:

- External communicating, tissue contacting, permanent duration and
- Surface contact, mucosal contact, permanent duration for the mouthpiece

The materials have been tested per ISO 10993-1 and ISO 18562.
Discussion: All associated materials in the gas or fluid pathway have been tested per ISO 10993-1 and ISO 18562 and found to meet the applicable requirements.

Bench Testing - We performed a series of non-clinical bench testing to demonstrate that the Maximus™ system is equivalent to the predicates. These tests included:

- Simulated Life Cycle testing including Cleaning
- Biocompatibility – Main Unit and Patient Circuit Components
  - ISO 10993
  - ISO 18562
- Software verification and validation
- Electrical safety, EMC
- Comparative Performance in CHFO, CPEP, Aerosol and MIE modes
- Comparative Nebulizer Performance across all therapy modes for adult and pediatric flow rates
- Inter- and Intra-sample variability and pre- and post-cleaning nebulizer performance
- Usability

The comparative testing demonstrates that the proposed device is substantially equivalent to the predicate devices.

Comparative Performance
We compared the proposed Maximus across all therapy modes vs. the applicable predicate and reference devices.
These tests included:

- Continuous High Frequency Oscillation (CHFO)
- Continuous Positive Expiratory Pressure (CPEP)
- Aerosol
- Comparative Bench Testing of MIE (Mechanical Insufflation-Exsufflation)
- Comparative Nebulizer Performance across all therapy modes for adult and pediatric flow rates

Discussion: The differences in some of the pressure limits is supported by the cleared reference devcies which have the same indications for use, patient population and environments of use. Any difference in performance or pressure limits do not raise new risk concerns and thus the Maximus™ system can be found to be substantially equivalent to the predicates.

Substantial Equivalence Conclusion
Based upon the risk analysis, comparative performance testing and the usability testing we have demonstrated that the proposed device and predicates can be found to be substantially equivalent.