May 26, 2020

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

Re: K200988
Trade/Device Name: Maximus System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: May 1, 2020
Received: May 4, 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)*

K200988

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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510(k) Summary

Date Prepared 26-May-20

Submission Sponsor:
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Sponsor Contact: Alvin Tan – R&D Executive Director

Submission Contact: Paul Dryden – ProMedic LLC

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: K192143 – Hill-Rom Maximus™ System

Device Description and Modification:
The modification is to add the ability to provide aerosol from the nebulizer via the Ventilator Tee adaptor during Continuous High Frequency Oscillations (CHFO) mode when connected to a ventilator. All components were cleared under K192143.

The Maximus™ System is a 2 in 1 device which combines 2 main types of therapies referred to as:

- MIE (Mechanical Insufflation-Exsufflation) – Synclara®
- OLE (Oscillation and Lung Expansion) - Volara™

The modified Maximus™ system and the predicate are presented in **Table 1.**

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 years 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

	Maximus™ System	**Predicate Maximus™ System**
510(k)		K192143
CFR Classification	868.5905 NHJ	868.5905 NHJ
Classification name	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)
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 expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.	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 expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.
Environments of Use	Hospital sub-acute facilities Nursing care Homecare	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	**Volara™ mode:** Adult, Child > 2 years old (acute) >5 year (home care) **Synclara™ mode:** Adult and pediatric
Therapy Modes	**Volara™ therapy modes:** CPEP, CHFO, Aerosol **Synclara™ therapy modes:** Inhale, Exhale, PAP	**Volara™ therapy modes:** CPEP, CHFO, Aerosol **Synclara™ therapy modes:** Inhale, Exhale, PAP
Available nebulizer	Philips SideStream (K991725)	Philips SideStream (K991725)
Aerosol delivery	Mouthpiece Face Mask Ventilator Tee Adaptor	Mouthpiece Face Mask
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.	Can connect via Bluetooth to Beijing Choice Electronic Technology Co., Ltd. Fingertip Pulse Oximeter, K142888. Only displays the heart rate and SpO_2 data.

	Modified Maximus™	Predicate Maximus™
Continuous Positive Expiratory Pressure (CPEP)	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, ≤ 70 cmH_2O
Aerosol	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only.	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only.
Maximum Positive Pressure	70 cmH_2O	70 cmH_2O
Maximum Negative Pressure	-70 cmH_2O	-70 cmH_2O
Inhalation, Exhalation and PAP duration	0 to 5 seconds	0 to 5 seconds
Flutter frequency	1 – 20 Hz	1 – 20 Hz
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.	**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.
Patient circuit settings	No resistance adjustment feature on patient circuit. Therapy settings are all done at the control unit.	No resistance adjustment feature on patient circuit. Therapy settings are all done at the control unit.
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.

	Modified Maximus™	Predicate Maximus™
Controller		
Principle of operation	Electro-Mechanical device Air or oxygen	Electro-Mechanical device 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 (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)

Performance of Aerosol Delivery in CHFO mode

We performed comparative particle characterization testing comparing the following patient interfaces: Mouthpiece, Face Mask (already cleared under K192143) and delivery through the already cleared Ventilator Tee Adaptor.

Testing was performed at Adult flow rates (28 Lpm) and Pediatric flow rates (12 Lpm) with 1 drug at the lowest and highest set pressures (5 and 70 cmH_2O). Testing parameters included the key particle parameters, Mass Median Aerodynamic Diameter (MMAD), Total Respirable Dose and Fine Particle, are equivalent. The comparative testing supports that the different patient interfaces are not significantly different in their delivery of aerosol.

Substantial Equivalence Discussion

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

Indications – The proposed indications for use for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and can provide supplemental oxygen when used with compressed oxygen are identical to the predicates.
Discussion: The indications for use are identical to the predicate.

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

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

Technology – The proposed modification is only related to the ability to deliver aerosol via the Ventilator Tee Adaptor when connected to a ventilator. The device itself is identical in hardware and software.
Discussion: The design of modified Maximus™ is identical to the predicate. The only performance testing was to demonstrate that the aerosol performance via the Ventilator Tee Adaptor was equivalent to the performance via a mouthpiece.

Discussion of Differences
The differences presented above have not raised new or different questions of safety or effectiveness from the predicate.

Non-clinical Performance

Biocompatibility of Patient Contacting Materials –
The materials in the gas and fluid pathway are identical to the predicate K192143. No further testing was required.

Bench Testing - We performed comparative nebulizer performance to demonstrate that the modified Maximus™ system is equivalent to the predicate. This test included:

- Comparative Nebulizer Performance across all therapy modes for adult and pediatric flow rates

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

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