October 24, 2018

Hill-Rom Holdings, Inc.
c/o Paul Dryden
Consultant for Hill-Rom
1 Yishun Ave 7
Singapore, 768923, Singapore

Re: K173603
Trade/Device Name: Monarch Airway Clearance System Model 1000
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: September 21, 2018
Received: September 24, 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. 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,

James J. Lee -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)*

K173603

Device Name

Monarch™ Airway Clearance System Model 1000

Indications for Use *(Describe)*

The Monarch™ product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The Monarch™ Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.

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: 23-Oct-18

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Official Contact: Joseph Braido
Vice President | Global Regulatory Affairs and Global Compliance

Tel – 312-819-9324

Proprietary or Trade Name: Monarch®Airway Clearance system Model 1000

Common/Usual Name: Electric-powered, percussor

Classification Code/Name: BYI – electric-powered, percussor
21 CFR 868.5665
Class II

Predicate Device: K163378 – Hill-Rom Monarch® Airway Clearance System Model 1000

Device Description:
The Monarch® Airway Clearance System Model 1000 (hereinafter referred to as Monarch®) consists of a garment which contains actuators together with the Main Control Box and pendant controller. The Main control box contains the electronics used to control the actuators which are organized into 8 discrete zones. The pendant controller is tethered to the garment and consists of an LCD display and selection controls to facilitate visual feedback of the therapy and system information while allowing the user to adjust the therapy settings to adhere to the prescribed therapy ordered by the physician.

It has adjustment mechanisms over each shoulder and on each side of the mid torso area to provide the wearer with a personal and evenly distributed snug fit. The buckles on each side of the device together with the front zipper help provide a repeatable fitting by allowing the wearer to wear and remove the garment without making changes to the adjustment mechanisms. The product also includes an external charger for the battery and can run on either power source as per desired by the user.

The major components to the Monarch® Airway Clearance System are:

- Garment – which contains the "pods"
- Garment shell – covers the underlying the garment
- Pendant – controls the device function
- Battery – installed in the backpack cover
- Garment adjustment mechanisms – means to secure and adjust the fit of the Garment to the user

This submission is specific to an expansion of the contraindication related to active implants. The device is identical to that cleared under K163378.

Indications for Use:

The Monarch® product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The Monarch® Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.

Table 1 – Substantial Equivalence Comparison to the Predicate and Reference Devices

Feature	Predicate	Subject Device
	Monarch® Airway Clearance System	**Monarch® Airway Clearance System**
	K163378	**- -**
Classification	BYI – Powered-electric Percussor 868.5665	
Indications for Use	The Monarch® product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging. The Monarch® Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.	The Monarch® product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging. The Monarch® Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.
Patient population	15 Years and older	15 Years and older
Expanded contraindication	• Recent placement of transvenous or subcutaneous pacemaker	The Monarch® device uses Pulmonary Oscillating Discs (PODs) that create a magnetic field which is present whether the device is turned on or off. Due to the presence of the magnetic field, people who have an active implantable medical device, such as any of the following, are contraindicated (if they cannot keep the susceptible component at least 6 inches away from the Monarch® device): • Pacemakers • Neurostimulators • Infusion Pumps including insulin pumps • Implantable Cardioverter Defibrillators (ICDs) • Circulatory Support Devices
Contraindications	• Head and/or neck injury that has not yet been stabilized • Active hemorrhage with hemodynamic instability • According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for Airway Clearance Therapy requires careful consideration and assessment of the individual patient's case if the following conditions exist: • Intracranial pressure (ICP) greater than 20 mm Hg	• Head and/or neck injury that has not yet been stabilized • Active hemorrhage with hemodynamic instability • According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for Airway Clearance Therapy requires careful consideration and assessment of the individual patient's case if the following conditions exist: • Intracranial pressure (ICP) greater than 20

	• Recent spinal surgery or acute spinal injury • Bronchopleural fistula • Pulmonary edema associated with congestive heart failure • Large pleural effusions or empyema • Pulmonary embolism • Rib fractures, with or without flail chest • Surgical wound or healing tissue or recent skin grafts or flaps on the thorax • Uncontrolled hypertension • Distended abdomen • Recent esophageal surgery • Active or recent gross hemoptysis • Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal • Subcutaneous emphysema • Recent epidural spinal infusion or spinal anesthesia • Burns, open wounds, and skin infections on the thorax • Suspected pulmonary tuberculosis • Lung contusion • Bronchospasm • Osteoporosis or osteomyelitis of the ribs • Coagulopathy • Complaint of chest wall pain	mm Hg • Recent spinal surgery or acute spinal injury • Bronchopleural fistula • Pulmonary edema associated with congestive heart failure • Large pleural effusions or empyema • Pulmonary embolism • Rib fractures, with or without flail chest • Surgical wound or healing tissue or recent skin grafts or flaps on the thorax • Uncontrolled hypertension • Distended abdomen • Recent esophageal surgery • Active or recent gross hemoptysis • Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal • Subcutaneous emphysema • Recent epidural spinal infusion or spinal anesthesia • Burns, open wounds, and skin infections on the thorax • Suspected pulmonary tuberculosis • Lung contusion • Bronchospasm • Osteoporosis or osteomyelitis of the ribs • Coagulopathy • Complaint of chest wall pain
Environment of Use	Home and ambulatory	Home and ambulatory
External manipulation of the chest	Yes	Yes
Vest with zones to direct oscillations	8 zones	8 zones
Principle of Operation / Technology	Vest with installed oscillating electromechanical actuators organized into eight zones which include permanent magnets as part of the actuators. Zipper, hook and loops on the front and shoulders for snug and evenly-distributed fit. Battery and AC/DC powered Remote wired into the Garment to adjust the intensity of the oscillation Bluetooth with App for optional control via Smartphone Wi-Fi for device usage data transmission	Vest with installed oscillating electromechanical actuators organized into eight zones which include permanent magnets as part of the actuators. Zipper, hook and loops on the front and shoulders for snug and evenly-distributed fit. Battery and AC/DC powered Remote wired into the Garment to adjust the intensity of the oscillation Bluetooth with App for optional control via Smartphone Wi-Fi for device usage data transmission
Technology of oscillations	Electromechanical actuators which have a static magnetic field of <1mT at ~ 1 inch (2.5cm) distance	Electromechanical actuators which have a static magnetic field of <1mT at ~ 1 inch (2.5cm) distance

Power sources	100 -240 VAC 24 V Battery	100 -240 VAC 24 V Battery
Modes	Manual Programmable Cough Pause	Manual Programmable Cough Pause
Therapy Peak Force across all settings	Peak Force (N) 2.2 to 25.9	Peak Force (N) 2.2 to 25.9
Components / Accessories	Garment cover Battery AC/DC adapter	Garment cover Battery AC/DC adapter
Biocompatibility	No direct patient contact Patient wears an undergarment	No direct patient contact Patient wears an undergarment
Electrical safety	ES 60601-1 CAN/CSA C22.2 No. 60601-1IEC 60601-1-2 IEC 60601-1-11	ES 60601-1 CAN/CSA C22.2 No. 60601-1IEC 60601-1-2 IEC 60601-1-11
Magnetic Interference Evaluation with Active Implants	Not tested	ISO14708 Clause 27.6 and 27.7 ISO 14117:2012 Clause 4.6 and 4.7
Operating conditions	Temp – 41 to 95°F Humidity – 15 to 90% Atmospheric pressure – 70 to 106 kPa	Temp – 41 to 95°F Humidity – 15 to 90% Atmospheric pressure – 70 to 106 kPa
Environmental conditions	Temp – -4 to 140°F Humidity – 15 to 90% Atmospheric pressure – 50 to 106 kPa	Temp – -4 to 140°F Humidity – 15 to 90% Atmospheric pressure – 50 to 106 kPa

Discussion of Substantial Equivalence

The Monarch® Airway Clearance System is substantially equivalent to the predicate because:

Indications – The Monarch® Airway Clearance System has the identical indications for use.
Discussion: The subject device indications, for use, therefore, do not raise different concerns of safety or effectiveness compared to the predicate. This includes the use of permanent magnets and their magnetic field and active implants.

Patient population – The Monarch® Airway Clearance System has the identical patient population of 15 years and older, as the predicate.

Environment of Use – The environment of use of a home care settings is identical to the predicate.

Technology – The technology of high frequency chest wall oscillation is identical to the predicate.
Discussion: The design and technology of the subject device is similar to the predicate which does not raise concerns of safety or effectiveness.

Non-clinical Comparative Performance

Electromagnetic Compatibility: We performed electromagnetic compatibility based upon ISO 14117:2012 for protection against static flux density of 1 mT and up to 50 mT.
Discussion: This confirmed that the static flux density is < 1 mT at 1 inch (2.5 cm) from the PODs. The contraindication for the Bystander states to remain at least 6 inches (15 cm) away. The results support the contraindication for the Bystander and are in alignment with the design and performance requirements of active implants.

Bench Testing -
The predicate for this 510(k) is the Monarch® Model 1000 (K163378) determined to be substantially equivalent itself, with no changes in the design or performance,

Biocompatibility –
There are no materials in direct contact with the patient.
Discussion: The user wears an undergarment which keeps any materials from direct contact.

Training –
Hill-Rom has a comprehensive program for patient in-service and training that is provided by qualified trainers. The patient specific training includes:

- Pre-qualified prior to training. They must meet the criteria specific to the contraindications
- Training includes the fitting and use of the device
- Reviewing specific instructions and guidelines related to product safety with the patient or caregiver
- Includes review of the Warnings and Contraindications regarding active implantable devices with the patient or caregiver, referring to the Monarch Airway Clearance System User Manual.

Human Factors / Usability Testing -
A knowledge assessment study was performed to test the participant's understanding of two knowledge tasks related to magnetic interference warnings. All participants passed.

Substantial Equivalence Conclusion

Based upon the risk analysis, performance testing and the usability testing we have demonstrated substantial equivalence.