DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 17, 2017

Hill-rom Services Pte Ltd
c/o Paul Dryden
Consultant for Hill-rom
1 Yishun Ave 7
Singapore North East 768923
SINGAPORE

Re: K163378
Trade/Device Name: Monarch™ Airway Clearance System
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: February 14, 2017
Received: February 15, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163378

Device Name

Monarch™ Airway Clearance System

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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510(k) Summary

14-Mar-17

Date Prepared 14-Mar-17

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Proprietary or Trade Name: Monarch™ Airway Clearance system

Common/Usual Name: Electric-powered, percussor

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

Predicate Device: K142482 – Hill-Rom – Vest® Model 105
Reference Device: K122480 – IBC – AffloVest

Device Description:
The Monarch™ Airway Clearance System 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 a 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 chest 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

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	Primary Predicate	Reference	Subject Device
	Hill-Rom Vest Model 105	**IBC AffloVest**	**Monarch™ Airway Clearance System**
	K142482	**K122480**	**- -**
Classification	BYI – Powered-electric Percussor 868.5665		
Indications for Use	The Vest® Airway Clearance Systems is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.	The International Biophysics Corporation AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment	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	Pediatric to Geriatrics	Not specified	15 Years and older

Feature	Primary Predicate	Reference	Subject Device
	Hill-Rom Vest Model 105	**IBC AffloVest**	**Monarch™ Airway Clearance System**
	K142482	**K122480**	**- -**
Environment of Use Homecare	Yes Others as well	Yes	Yes
External manipulation of the chest	Yes	Yes	Yes
Vest with zones to direct oscillations	No zones	6 zones	8 zones
Principle of Operation / Technology	Vest with air pockets that are filled by a remote air generators Buckles and straps on the front and shoulders for snug and evenly-distributed fit. AC/DC powered Remote wired into the vest for start, stop, pause Bluetooth for data transmission only	Vest with installed oscillating vibratory motors organized into six zones. Buckles and straps on the front and shoulders for snug and evenly-distributed fit. Battery and AC/DC powered Remote wired into the vest to adjust the intensity of the oscillation	Vest with installed oscillating electromechanical actuators organized into eight zones. 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	Controller which generates air pockets	Electric motors	Electromechanical actuators
Power sources	110 VAC	110 VAC 22.2 V Battery	110 VAC 24 V Battery
Modes	Manual Programmable Cough Pause	9 pre-set programs	Manual Programmable Cough Pause
Therapy Peak Force across all settings	Peak Force (N) 3.1 to 31.7	Peak Force (N) 4.9 to 9.5	Peak Force (N) 2.2 to 25.9
Acoustic energy	82.8 dBA @ 1 m	48 dBA @1 m	43.6 dBA @ 0.3 m per IEC 60601-1 clause 9.6.2
Weight of worn components	1.0 kg	5.4 kg	6.0 kg
Useful life of External Shell	5 years / 60 cleaning cycles	- -	5 years / 60 cleaning cycles
Components / Accessories	Garment cover Supply hose Air generator controller	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	No direct patient contact Patient wears an undergarment
Electrical safety	ES 60601-1 CAN/CSA C22.2 No. 60601-1	Not specified	ES 60601-1 CAN/CSA C22.2 No. 60601-1IEC 60601-1-2 IEC 60601-1-11
Operating conditions	Temp – 41 to 95^{o}F Humidity – 15 to 95% Atmospheric pressure – 70 to 106 kPa	Temp – 41 to 95°F Humidity - 15 - 93% Atmospheric pressure - 70 – 106 kPa	Temp – 41 to 95^{o}F Humidity – 15 to 90% Atmospheric pressure – 70 to 106 kPa
Environmental conditions	Temp – -4 to 140^{o}F Humidity – 15 to 90% Atmospheric pressure – 50 to 106 kPa	Temp – 68 to 122°F Humidity – 0 to 93%	Temp – -4 to 140^{o}F Humidity – 15 to 90% Atmospheric pressure – 50 to 106 kPa

Feature	Primary Predicate	Reference	Subject Device
	Hill-Rom Vest Model 105	**IBC AffloVest**	**Monarch™ Airway Clearance System**
	K142482	**K122480**	**- -**
Operating conditions	Temp – 41 to 95°F Humidity – 15 to 95% Atmospheric pressure – 70 to 106 kPa	Temp – 41 to 95°F Humidity - 15 - 93% Atmospheric pressure - 70 – 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 – 68 to 122°F Humidity – 0 to 93%	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 viewed as substantially equivalent to the predicate and reference devices because:

Indications – The Monarch™ Airway Clearance System has similar indications for use related to airway clearance via chest wall oscillation.
Discussion: The subject device is indications for use there are no new concerns of safety or effectiveness for the proposed indication.

Patient Population – The Monarch™ Airway Clearance System has a patient population of 15 years and older which is within the age range of the predicate and reference.
Discussion: The subject device has a narrower patient range than the predicate and reference devices, but this does not raise any new concerns of safety or effectiveness.

Environment of Use – The environment of use for home care settings is similar to the predicate Hill-Rom Vest Model 105, K142482, which has a broad range of environments.
Discussion: The subject device has a narrower environment of use as this is the target market. This difference does not raise any new concerns of safety or effectiveness.

Technology – The technology of high frequency chest wall oscillation is similar to the predicate and reference devices.
Discussion: The design and technology of the subject device is similar to the reference device. In that the characteristics of the use of an electrical actuator / motor operated in zones in a vest. Whereas the predicate uses air pockets with no specific zones to generate oscillation throughout the whole chest area vs. specific areas (zones) of the chest. We performed comparative testing demonstrating the difference of how the oscillations are generated is equivalent in the generation of force and frequency to the predicate and the reference devices.

Performance – The performance features and parameters were compared to the predicate and reference devices and the subject device as intended performs in-between the 2 devices.
Discussion: We performed comparative testing across all modes and the performance results were substantially equivalent.

Non-clinical Comparative 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. This is similar to the predicate and reference devices.

Bench Testing -
We performed a series of non-clinical bench testing to demonstrate equivalence to the predicate and reference devices. These tests included:

- Peak Force of the vest against the chest of a mannequin - comparison
    - Measured at different chest locations
    - Frequencies - low, middle and high range of the device
    - Intensity levels - low, middle, high range
    - Objective was that the Monarch performance would be higher than AffloVest (K122480) but below the predicate Vest Model 105 (K142482)
- Durability of Garment Cover to cleaning
- Simulated Life Cycle testing
- Usability – home environment

All the testing demonstrates that the Monarch™ Airway Clearance System met its performance specifications and / or is substantially equivalent to the identified predicate or reference devices.

Human Factors / Usability Testing -
Hill-Rom conducted a human factors (HF) validation usability test of Hill-Rom's Monarch Airway Clearance System. The test's goal was to evaluate the extent to which representative users can interact with the device.

The human factors validation test included individuals representing two distinct user groups.

Substantial Equivalence Conclusion

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