December 21, 2018

NormaTec Industries, LP
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K183328
Trade/Device Name: Pulse Rx 2.0, Pulse Pro Rx 2.0
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 27, 2018
Received: November 30, 2018

Dear Mark Job:

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,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*

K183328

Device Name
Pulse Rx 2.0, Pulse Pro Rx 2.0

Indications for Use *(Describe)*

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 are intended to apply pressure to the extremities to treat: lymphedema and other edematous conditions, including congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda), post-mastectomy lymphedema, post-infection lymphedema, post-traumatic lymphedema, post-surgical lyphedema, post-radiation treatment lymphedema, venous insufficiency, venous stasis ulceration, and to prevent Deep Vein Thrombosis.

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

☒ 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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NormaTec Industries, LP

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Official Contact:	Albert G Sanford, Quality Systems and Regulatory Manager
Proprietary or Trade Name:	Pulse Rx 2.0 and Pulse Pro Rx 2.0
Common/Usual Name:	Compressible limb sleeve
Classification Code and Name:	21 CFR 870.5800 Compressible Limb Sleeve Product Code: JOW Class II
Device Name:	Pulse Rx 2.0, and Pulse Rx 2.0
Predicate Device:	K161346 – NormaTec PCD-B and NormaTec PCD-T

Device Description

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 are Compressible Limb Sleeves (Product Code "JOW"). They simulate manual kneading and stroking of tissues by use of an inflatable pressure cuff. The devices are powered by an external IEC 60601-1 Power Supply and can also be powered by an internal IEC 62133-compliant lithium-ion battery.

The user interface on the Pulse Pro Rx 2.0 model is 4.3” color TFT Screen with capacitive sensor (similar to a Smartphone). The user interface on the Pulse Rx 2.0 model is 4.3” color LCD screen with smart switches. There is no difference in function between the two interface technologies, they are offered for marketing differentiation and user preferences. The user interface provides for:

- Starting and stopping the massage treatment;
- Adjusting time and intensity (pressure) of the treatment.

In addition to the user interface on the devices, the proposed devices have Bluetooth capability that allows the use of a NormaTec app to control the device. The Bluetooth app mimics the device interface graphics and buttons, allowing the user to use a compatible Android or iOS phone to control device functions just as if they were using the interface on the device. The app functionality is limited to mimicking the device interface and does not provide or unlock any additional features or alter the therapy provided by the device.

Intended User

Rx Only

Patient Population

Adults

Indications for Use

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 are Compressible Limb Sleeves intended to apply pressure to the extremities to treat Lymphedema and other edematous conditions, including:

- Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda)
- Post-mastectomy lymphedema
- Post-infection lymphedema
- Post-traumatic lymphedema
- Post-surgical lymphedema
- Post-radiation-treatment lymphedema
- Venous insufficiency
- Venous stasis ulceration

and to prevent Deep Vein Thrombosis

Intended Use Environment:

Home, hospital, and other healthcare settings.

Table 5.1 – Table of Device Comparisons and Differences

	Predicate Devices	Proposed New Devices	Comment
Model Name 510(k) Number	NormaTec PCD-B and NormaTec PCD-T 510(k) K161346	NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 510(k) TBD	N/A
Manufacturer	NormaTec Industries, LP	Same	N/A
Prescriptive	Yes	Same	N/A
Indications for use	The NormaTec PCD-B and PCD-T are compressible limb sleeves intended to apply pressure to the extremities to treat Lymphedema and other edematous conditions, including: • Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda) • Post-mastectomy lymphedema • Post-infection lymphedema • Post-traumatic lymphedema • Post-surgical lymphedema • Post-radiation-treatment lymphedema • Venous insufficiency • Venous stasis ulceration and to prevent Deep Vein Thrombosis	Same	N/A
Intended Use Environment	Home, hospital, and other healthcare settings.	Same	N/A
Power Source(s)	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input). Optional internal battery.	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input). Intergrated rechargeable battery	N/A

	Predicate Devices	Proposed New Devices	Comment
Software / Firmware Micro-processor Control	Microprocessor	Same	N/A
Technology	Compressor and valve system that sequentially inflates cells of appliance	Compressor and valve system that sequentially inflates cells of appliance. Bluetooth communication ability.	Proposed devices incorporate a certified Bluetooth module to allow using a NormaTec app as a user interface.
Compliance with Voluntary standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ANSI C63.27-2017.	The proposed devices comply with one additional standard: ANSI C63.27-2017
Device Pressure Range	Same	Same	N/A
Treatment Time	Stays on until the user turns it off or can be set up to turn off in a range of 10 to 175 minutes	Stays on until the user turns it off or can be set up to turn off in a range of 10 minutes to continuous	N/A
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	Same	N/A
Appliance Contact Surface Material	200 denier nylon with a polyurethane laminate/extrusion	Same	N/A
Number of Inflatable appliance segments	5 or less	Same	N/A
Weight	3.6 pounds (incl. battery)	Same	N/A
Dimensions (W x H x D)	4” x 5” x 9”	4.4” x 3.8” x 8.1”	N/A
Housing Materials and Constructions	Molded ABS enclosure (94V0)	Same	N/A
Patient contact	Non-conductive appliances	Same	N/A

Differences Between Models

Characteristic	Pulse Rx 2.0	Pulse Pro Rx 2.0
Power On – The system recalls and displays the last used settings for:		
Treatment time	X	X
Treatment mode	X	X
Therapy mode Rehab mode – Recalls zone focus Custom – recalls all settings Recovery Flush	X	X
Appliance Type	N/A	X
Power Level	X	X
Number of zones	X	X
Rest time	X	X
Time		
Add time Before treatment During treatment	X	X
Decrease time Before treatment During treatment	X	X
Continuous mode	X	X
Counter Count down – 1 second increments Count up (continuous mode) – 1 second increments	X	X
Compliance – Trip meter – reset by User	N/A	X
Chronometer Odometer – cannot be reset by User	X	X
Pressure		
Increase level Before treatment During treatment	X	X
Decrease level Before treatment During treatment	X	X

Characteristic	Pulse Rx 2.0	Pulse Pro Rx 2.0
Treatment Mode – Can ONLY be changed before treatment begins		
NormaTec Pulse	X	X
Sequential	X	X
Rest Time		
View or change rest time – before treatment	X	X
# of Zones		
Change number of zones – before treatment	X	X
Treatment		
Starting	X	X
Pause	X	X
Un-pause	X	X
End – If timer reaches $0:00^{00}$, treatment will continue until Rest period is reached. The user is given options to either: Add time Continue until cycle is finished Quit	X	X
Remote operation via Bluetooth app	X	X
Battery Charging		
Displays battery level	X	X
Displays when battery is charging	X	X
Power off		
No treatment in process	X	X
Treatment is process	X	X
Appliance type		
Select appliance – boot, arm, hip NOTE: If hip appliance is selected, treatment mode defaults to 2-zone treatment	X	X
Therapy Mode		
Recovery Flush Preset NormaTec PULSE time / PULSE pressure values Appliance type applicable – boot, arm, hip	N/A	X
Rehab Preset NormaTec PULSE time / PULSE pressure values Leg appliance – Foot/ankle, calf, knee, lower quad, upper quad Arm appliance – Hand/wrist, forearm, elbow, bicep, shoulder Hip appliance – Quadriceps, hip	N/A	X

Characteristic	Pulse Rx 2.0	Pulse Pro Rx 2.0
Custom Settings Allows user to program NormaTec PULSE pressure and time values for each zone Pressure range – 30-110 mmHg, user can select in 10 mmHg increments Time range – 15 seconds to 4 minutes, user can select in 15 second increments	N/A	X
Display Settings Adjustment		
Brightness controls	N/A	X

Determination of Substantial Equivalence

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 are substantially equivalent to currently marketed and cleared devices NormaTec PCD-B and NormaTec PCD-T 510(k) K161346 because:

Indications for Use

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 indications for use are identical to the predicate device, NormaTec PCD-B and NormaTec PCD-T 510(k) K161346.

Prescriptive

The NormaTec Pulse Rx 2.0, Pulse Pro Rx 2.0, and the predicate (K161346) are Rx devices.

Design, Technology, and Principle of Operation

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 have equivalent design and features when compared to the predicate and have the equivalent technology to the predicate, NormaTec PCD-B and NormaTec PCD-T 510(k) K161346.

The proposed devices have Bluetooth capability that allows the use of a NormaTec app to control the device. The Bluetooth app mimics the device interface graphics and buttons, allowing the user to use a compatible Android or iOS phone to control device functions just as if they were using the interface on the device. The app functionality is limited to mimicking the device interface and does not provide or unlock any additional features or alter the therapy provided by the device.

Performance and Specifications

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 have equivalent specifications of performance when compared to the predicate, NormaTec PCD-B and PCD-T 510(k) K161346.

Compliance with Standards

The predicate devices are compliant with AAMI ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-1-11.

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 comply with AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and ANSI C63.27-2017.

Materials

The patient-contacting materials of the Pulse Rx 2.0 and Pulse Pro Rx 2.0 are the inflatable appliances that are identical to the predicate, NormaTec PCD-B and PCD-T 510(k) K161346.

Intended Use Environment

Home, hospital, and other healthcare settings, which are identical to the predicate.

Features

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 have equivalent features when compared to the predicate, NormaTec PCD-B and PCD-T 510(k) K161346.

Conclusion

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 are substantially equivalent to the predicate, NormaTec PCD-B and PCD-T 510(k) K161346 in:

- Patient population,
- Environment of use,
- Technology characteristics,
- Materials,
- Specifications / performance, and
- Compliance with international standards.

The inclusion of the Bluetooth capability and associated app does not affect the equivalency of the proposed devices and the predicate. The app functions only as an alternative user interface. No additional features are provided or unlocked by the app. Nor is the therapy provided by the devices affected by using the app.

Other minor differences as detailed in the substantial equivalence table do not raise questions of safety and effectiveness.

Indications for Use

The NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 Indications for Use and Contraindications are identical to the predicate device, NormaTec PCD-T and NormaTec PCD-B 510(k) K161346.

Verification and Validation activities required that establish the performance, functionality, and reliability characteristics of the NormaTec Pulse Rx 2.0 and Pulse Pro Rx 2.0 with respect to the predicate were performed. Testing performed demonstrated that the proposed devices meet defined requirements and performance claims.