DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 15, 2016

NormaTec Industries, LP
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K161346
Trade/Device Name: NormaTec PCD-T and NormaTec PCD-B
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 13, 2016
Received: May 16, 2016

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. 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" (21CFR 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 yours,

Nicole G. Ibrahim -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K161346

Device Name

NormaTec PCD-T and NormaTec PCD-B

Indications for Use *(Describe)*

The NormaTec PCD-T and NormaTec PCD-B 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 lymphedema
- 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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510(k) Summary

Official Address:	NormaTec Industries, LP 44 Glen Ave Newton, MA 02459 Tel – 617 658 5827 Fax – 617 928 3407
Official Contact:	Peter Novello – Director Manufacturing and Regulatory
Proprietary or Trade Name:	NormaTec PCD-T and NormaTec PCD-B
Common/Usual Name:	Compressible limb sleeve
Classification Name/Code:	JOW - Compressible limb sleeve. Class II
Device Name:	NormaTec PCD-T and NormaTec PCD-B
Predicate Devices:	K013436 – NormaTec PCD

Device Description:
The NormaTec PCD-T and PCD-B are designed to provide noninvasive air compression therapy for the treatment of lymphedema, venous insufficiency, other edemas, and venous stasis ulceration and to prevent deep venous thrombosis.
They simulate manual kneading and stroking of tissues by use of an inflatable pressure cuff. The devices are powered from an external IEC 60601-1 compliant power supply and can optionally be powered by an internal lithium ion battery.

The NormaTec PCD-T and PCD-B consist of an air compressor unit with a control system, an inflatable "appliance" (arms, legs and hips), plastic air tubing with proprietary connectors for connecting the device to the appliance; and an AC-DC adaptor with power cord.

The inflatable leg and arm "appliances" and the plastic air tubing are of the same general design and constructions as those cleared in the predicate NormaTec PCD (K013436) the materials are identical. The hip appliance is identical to that in NormaTec's Pulse and Pulse Pro massagers cleared in 510(k) K160608 and uses identical materials.
Additionally, the air compressor, valve, valve control are similar to the predicate NormaTec PCD (and are identical to the NormaTec's Pulse and Pulse Pro massagers cleared in 510(k) K160608)

510(k) Summary

The user interface on the PCD-T model is a 4.3”Color TFT Screen with Capacitive Sensor (similar to a Smartphone). The user interface on the PCD-B model is 4.3” Color LCD Screen, with Membrane Keypad with dome switches. There is no difference in function between the two interface technologies, they are just being offered for slight feature differences and user preferences.

Intended User
Lay users and professional

Patient Population
Adults

Indications for Use:
The NormaTec PCD-T and PCD-B 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 lymphedema
- Post-radiation-treatment lymphedema
- Venous insufficiency
- Venous stasis ulceration

and to prevent:
Deep Vein Thrombosis

Environment of Use:
Home, hospital or other health care setting

Contraindications:
Contraindicated for patients with acute Deep Vein Thrombosis.
This contraindication is identical to the predicate.

510(k) Summary

Differences Between the PCD-T and PCD-B

The table below details features available on PCD-T that are not available on PCD-B

Characteristic	PCD-B	PCD-T
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
Appliance type		X
Power level	X	X
Number of zones	X	X
Rest time	X	X
Brightness settings		X
Time		
Add time ☐ Before treatment ☐ During treatment	X	X
Decrease time ☐ Before treatment	X	X
☐ During treatment		
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		X
Chronometer Odometer – cannot be reset by User		X
Pressure		
Increase level ☐ Before treatment ☐ During treatment	X	X
Decrease level ☐ Before treatment ☐ During treatment	X	X
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

510(k) Summary

Battery charging		
Displays battery level	X	X
Displays when battery is charging	X	X
Power off		
No treatment in process	X	X
Treatment in process	X	X
Appliance type		
Select appliance type – boot, arm, hip *Note: If hip appliance is selected, treatment mode defaults to 2-zone treatment*		X
Therapy mode		
Recovery flush ☐ Preset Pulse time / Pulse pressure values ☐ Appliance type applicable – Boot, arm, hip		X
Rehab ☐ Preset 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		X
Custom Settings		X
☐ Allows user to program NormaTec Pulse pressure and time values for each zone ☐ Pressure range – 30-100 mmHg, user can select in 10mmHg increments ☐ Time range – 15 seconds to 4 minutes, user can select in 15 second increments		
Display settings adjustment		
Brightness controls		X

Predicate Device Comparison:

The PCD-T and PCD-B were compared to the predicate NormaTec PCD - K013436 in the device comparison table below, also includes is a table that shows equivalence to a reference device NormaTec Pulse and Pulse Pro for the hip appliance.

510(k) Summary

Model Name **510(k) Number**	**New Device** **NormaTec PCD-T and PCD-B** **510(k) TBD**	**Predicate Device** **NormaTec PCD** **510(k) K013436**	**Comment**
Manufacturer	NormaTec Industries	NormaTec Industries	-
Indications for use	The NormaTec PCD-T and PCD-B 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 lymphedema • Post-radiation-treatment lymphedema • Venous insufficiency • Venous stasis ulceration and to prevent: Deep Vein Thrombosis	The NormaTec PCD is 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	Identical
Contraindications	Contraindicated for patients with acute Deep Vein Thrombosis.	Contraindicated for patients with acute Deep Vein Thrombosis.	Identical
Prescriptive	Rx	Rx	Identical
Power Source(s)	12 DC via an IEC 60601-1 compliant power supply (100-240 VAC input) Optional Integrated rechargeable battery	12 DC via an IEC 60601-1 compliant power supply (100-240 VAC input)	PCD-T and PCD-B have an optional integral battery not required for function.
Software/Firmware/Microprocessor Control	Microprocessor	Microprocessor	Same control technology
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Identical technology
Compliance with Voluntary standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2	PCD-T and PCD-B comply with currently recognized version of 60601-1

			and home use standard
Device Pressure range	30 - 110 mmHg	30 - 110 mmHg	Identical
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	Added ability to time treatment
Inflation/deflation cycle type	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Identical
Appliance contact surface material	200 denier nylon with a polyurethane laminate/extrusion	200 denier nylon with a polyurethane laminate/extrusion	Identical
Number of Inflatable appliance segments	5 or less	5 or less	Identical
Weight	3.6 pounds (incl. battery)	14 pounds	Similar
Dimensions (W x H x D)	4" x 5" x 9"	14.2" x 8.6" x 12.3"	Similar
Housing Materials and Constructions	Molded ABS enclosure (94V0)	Thermoplastic	Similar
Patient contact	Non-conductive appliances	Non-conductive appliances	Identical

Model Name 510(k) Number	**New Device NormaTec PCD-T and PCD-B 510(k) TBD**	**Predicate Device NormaTec PCD 510(k) K013436**	**Reference Device NormaTec Pulse and Pulse Pro 510(k) K160608**	**Comment**
Appliances	Leg, Arm, Hip	Leg, Arm	Leg, Arm, Hip	Leg and arm appliances are same design and construction as those cleared in 510(k) K013436. The leg , arm and hip appliances are identical to those cleared in 510(k) K160608

510(k) Summary

Performance Testing

Bench:

The device has been tested to ensure that it all requirements have been met, this includes:

- Testing of all controls
- Testing of all indicators
- Testing of battery state indicators
- Testing of performance
- Testing of hazard mitigations

The device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 Medical electrical equipment - part 1: general requirements for basic safety and essential performance

- IEC 60601-1-2: 2007 Collateral standard: Electromagnetic Compatibility - Requirements and Tests

- IEC 60601-1-11: 2010, Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Animal:

No animal testing was performed

Clinical:

No clinical testing was performed

Conclusion

The NormaTec PCD-T and PCD-B are substantially equivalent to the predicates in: indications for use, contraindications, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. Minor differences as detailed in the substantial equivalence table above do not raise questions of safety and effectiveness.