DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2016

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

Re: K160608
Trade/Device Name: NormaTec Pulse and NormaTec Pulse Pro
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 28, 2016
Received: March 29, 2016

Dear Mr. 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" (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 yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160608

Device Name
NormaTec Pulse and NormaTec Pulse Pro

Indications for Use *(Describe)*
The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

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

K160608

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 Pulse and NormaTec Pulse Pro

Common/Usual Name: Powered inflatable tube massager.

Classification Name/Code: IRP - Powered inflatable tube massager

Class II

Device Name: NormaTec Pulse and NormaTec Pulse Pro

Predicate Devices: K112890 – NormaTec MVP
K122154 - Figg, LLC PowerPlay model PPRT-01

Device Description:
The NormaTec Pulse and Pulse Pro are powered inflatable tube massagers. They are intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. They simulate manual kneading and stroking of tissues by use of an inflatable pressure cuff. The device is to be used by people who are in good health. 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 Pulse and Pulse Pro 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 identical to the components of the FDA-cleared NormaTec MVP (K112890). The hip appliance is of the same general design and uses identical materials. Additionally, the air compressor, valve, valve control are similar to the predicate NormaTec MVP.

The user interface on the Pulse Pro model is a 4.3"Color TFT Screen with Capacitive Sensor (similar to a Smartphone). The user interface on the Pulse 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.

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Intended User
OTC

Patient Population
Adults

Indications for Use:
The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Environment of Use:
Clinics, hospital, athlete training, and home environments

Contraindications:

- Do not use this product if you are experiencing inflammation, an infection, pain of unknown origin, or bleeding (internal or external) at or near the site of application or if you have a wound at or near the site of application.
- Do not use this product if you are under the care of a physician or have a condition requiring the use of any medical device.
- Do not use this product on sensitive skin or on in the presence of poor circulation.
- Do not use this product if you have any of the following conditions:
    - Acute pulmonary edema
    - Acute thrombophlebitis
    - Acute congestive cardiac failure1
    - Acute infections
    - Deep Vein Thrombosis (DVT)
    - Episodes of Pulmonary embolism
    - Wounds lesions or tumors at or in the vicinity of application
    - Where increased venous and lymphatic return is undesirable
    - Bone fractures or dislocations at or in the vicinity of application

These contraindications are identical to the predicate.

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Differences Between Pulse and Pulse Pro

The table below details features available on Pulse Pro that are not available on Pulse

Characteristic	PULSE	PULSE PRO
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

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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
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

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Predicate Device Comparison:

The Pulse and Pulse Pro were compared to the predicates NormaTec MVP - K112890 and Figg PowerPlay model PPRT-01 - K122154 in the device comparison tables below.

Model Name 510(k) Number	**Subject Device K160608 NormaTec Pulse and Pulse Pro**	**Predicate Device K112890 NormaTec MVP**	**Comment**
Manufacturer	NormaTec Industries	NormaTec Industries	Identical
Indications for use	The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The NormaTec MVP is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Identical
Contraindications	Specified below	Specified below	Identical
Prescriptive or OTC	OTC	OTC	Identical
Power Source(s)	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Optional Integrated rechargeable battery	12 VDC via an IEC 60601-1 compliant power supply (100 - 240 VAC input)	Pulse and Pulse Pro have an optional integral battery not required for function.
Software/Firmware/Microprocessor Control	Microprocessor	Analog	Software provides identical control functionality, additionally provides visual feedback
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,	Pulse / Pulse Pro complies 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 mins to continuous	Stays on until the user turns it off	Added ability to time treatment

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Inflation/deflation cycle type	Sequential Gradient, Peristaltic and	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)	8 pounds	Similar
Dimensions (W x H x D)	4" x 5" x 9"	11" x 6.5" x 7"	Similar
Housing Materials and Constructions	Molded ABS enclosure (94V0)	Thermoplastic	Similar
Patient contact	Non-conductive appliances	Non-conductive appliances	Identical
Appliances	Leg, Arm, Hip	Leg, Arm	Leg and Arm appliances are identical to 510(k) K112890. A hip appliance is available as part of predicate K122154

Parameter	**Subject Device K160608 NormaTec Pulse and Pulse Pro**	**Predicate K122154 Power Play**	**Comment**
Treatment Time	User controlled 10 minutes to 175 minutes or continuous –total time over 4 segments	20 minutes max per port (segments)	The Pulse and Pulse Pro allow the user to adjust the treatment time while the predicate device (K112154) time is fixed at 20 minutes. There is no impact to safety or effectiveness with this adjustable option and ability to select a longer treatment time with the hip appliance.
Pressure Range	30-110 mmHG	30-70 mmHG	The Pulse and Pulse Pro have a broader pressure range than the predicate device (K112154) with maximum pressure of

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			110mmHG. This pressure is the same maximum used on the Pulse and Pulse Pro Arm and Leg appliances (and predicate NormaTec MVP 510(k) K112890). As the hip area is a larger body mass than the arm and leg appendages, this higher pressure presents no compromises to safety or effectiveness to the user wearing the hip appliance.
Inflation Cycle / Pulsing	Preinflate ,then either sequential or peristaltic Pulsing as selected by user -with adjustable rest time	Preinflate, rest, deflate then repeat the sequencing	The Pulse and Pulse Pro have 2 different massage patterns that can be selected by the user as well as having the option to adjust the rest time. The predicate device (K112154) has a predetermined cycle and rest-time. There is no impact of safety or effectiveness with the differences in the massage patterns between the NormaTec and the predicate's hip appliances.

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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 + A1: 2012 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 Pulse and Pulse Pro 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.