February 25, 2022

NormaTec Industries, LP
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220217
Trade/Device Name: Normatec 3
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 25, 2022
Received: January 26, 2022

Dear Prithul Bom:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220217

Device Name
Normatec 3

Indications for Use *(Describe)*
The Normatec 3 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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NormaTec Industries, LP

Date of Preparation: February 22, 2022

480 Pleasant Street
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Watertown MA 02472

Tel – 800.355.0960
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Official Contact: Steve Henderson, Quality Systems and Regulatory Manager

Proprietary or Trade Name:	Normatec 3
Subject Device:	Normatec 3
Common/Usual Name:	Massager, Powered Inflatable Tube
Classification Name	Powered inflatable tube massager
Regulation Number:	21 CFR 890.5650
Product Code:	IRP
Regulation Medical Speciality:	Physical Medicine
Predicate Device:	K183169 – NormaTec Pulse 2.0 and Pulse Pro 2.0
Classification Name	Powered inflatable tube massager
Common/Usual Name	Massager, Powered Inflatable Tube
Regulation Number:	21 CFR 890.5650
Product Code	IRP
Regulation Medical Speciality:	Physical Medicine

Device Description

The Normatec 3 is a powered inflatable tube massager (Product Code "IRP"). It is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. It simulates manual kneading and stroking of tissues by the use of an inflatable pressure cuff. The devices are 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 also be powered by an internal IEC 62133-2 compliant lithium-ion battery.

The user interface on the Normatec 3 is a series of buttons with one small display screen to display the treatment time. The user interface provides for:

- Starting and stopping the massage treatment;
- Adjusting time and intensity (pressure) of the treatment;
- Selection of Attachment in use (Leg, Arm, Hip);
- Selection of Zone Boost which provides an increase of 10 mm Hg to the Zone selected

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 allows the user to use a compatible Android or iOS phone to select and set device parameters listed above for convenience.

Intended User

OTC

Patient Population

Adults

Indications for Use

The NormaTec Normatec 3 is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Intended Use Environment:

Clinics, hospital, athlete training, and home environments.

Table 1 – Table of Device Comparisons and Differences

	Predicate Device	Proposed New Device	Comment
Model Name 510(k) Number	NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169	Normatec 3 510(k) K220217	N/A
Manufacturer	NormaTec Industries, LP	Same	N/A
Prescriptive	No, OTC	Same	N/A
Indications for use	The NormaTec Pulse 2.0 and Pulse Pro 2.0 are air pressure massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The NormaTec Normatec 3 is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	N/A
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Same	N/A
Power Source(s)	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input) Integrated rechargeable battery	Same	N/A
Software / Firmware Micro-processor Control	Microprocessor	Same	N/A
Technology	Compressor and valve system that sequentially inflates cells of appliance. Bluetooth communication ability.	Same	N/A
Compliance with Voluntary standards	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11 and ANSI C63.27-2017.	Same and includes IEC 60601-1-6 compliance	The additional testing of 60601-1-6 compliance does not raise any new device safety concerns

	Predicate Device	Proposed New Device	Comment
Device Pressure Range	0-110 mmHg	Same	N/A
Pressure Levels	Level 1: 40 mm Hg max Level 2: 50 - 60 mm Hg max Level 3: 60 - 70 mm Hg max Level 4: 70 - 80 mm Hg max Level 5: 80 mm Hg max Level 6: 80 - 90 mm Hg max Level 7: 100 mm Hg max	Same	N/A
ZoneBoost	Provides an increase of 10 mm Hg to the Zone selected	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 minutes to continuous	Stays on until the user turns it off or can be set up to turn off in a range of 15 minutes to 60 minutes	Changed setup times for treatment of new device to a max of 60 minutes instead of continuous to match user typical sessions with device.
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)	4.4” x 3.8” x 8.1”	4.17 x 3.66 x 8.25	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 2.0 / Pulse Pro 2.0	Normatec 3
Power On – The system recalls and displays the last used settings for:		
Treatment time	X	X
Treatment mode	X	N/A
Therapy mode Rehab mode – Recalls zone focus Custom – recalls all settings Recovery Flush	Pulse 2.0 – N/A Pulse Pro 2.0 – X	N/A
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	Pulse 2.0 – N/A Pulse Pro 2.0 – X	N/A
Appliance Type	Pulse 2.0 – N/A Pulse Pro 2.0 – X	X
Pressure 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	N/A
Counter	X	X
Count down – 1 second increments	X	X
Count up (continuous mode) – 1 second increments	X	N/A
Compliance – Trip meter	Pulse 2.0 – N/A Pulse Pro 2.0 - X	X
Chronometer Odometer – cannot be reset by User	X	X
Pressure		

Characteristic	Pulse 2.0 / Pulse Pro 2.0	Normatec 3
Increase level Before treatment During treatment	X	X
Decrease level Before treatment During treatment	X	X

Characteristic	Pulse 2.0 / Pulse Pro 2.0	Normatec 3
Treatment Mode – Can ONLY be changed before treatment begins		
NormaTec Pulse	X	X
Sequential	X	N/A
Rest Time		
View or change rest time – before treatment	X	N/A
# of Zones		
Change number of zones – before treatment	X	N/A
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.	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	Pulse 2.0 – N/A Pulse Pro 2.0 – X	N/A
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	Pulse 2.0 – N/A Pulse Pro 2.0 – X	N/A

Characteristic	Pulse 2.0 / Pulse Pro 2.0	Normatec 3
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	Pulse 2.0 – N/A Pulse Pro 2.0 - X	N/A
Display Settings Adjustment		
Brightness controls	Pulse 2.0 – N/A Pulse Pro 2.0 - X	N/A

Determination of Substantial Equivalence

The Normatec 3 is substantially equivalent to currently marketed and cleared devices (K183169) because:

Indications for Use

The Normatec 3 indications for use are identical to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0, 510(k) K183169.

Prescriptive

The Normatec 3 and the predicate (K183169) are OTC devices.

Design, Technology, and Principle of Operation

The Normatec 3 has equivalent design and features when compared to the predicate and have similar technology to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169.

The proposed device has Bluetooth capability that allows the use of a NormaTec app to control the device. In addition to the user interface on the devices, the proposed device has Bluetooth capability that allows the use of a NormaTec app to control the device. The Bluetooth app allows the user to use a compatible Android or iOS phone to select and set device parameters listed above for convenience.

Performance and Specifications

The Normatec 3 has equivalent specifications of performance when compared to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169.

Compliance with Standards

The predicate devices are compliant with AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11 and ANSI C63.27-2017.

The Normatec 3 complies with AAMI ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and ANSI C63.27-2017.

Materials

The patient-contacting materials of the Normatec 3 are the inflatable appliances that are identical to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169.

Intended Use Environment

Clinics, hospital, athlete training, and home environments, which are identical to the predicate.

Features

The Normatec 3 has equivalent features when compared to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169.

Conclusion

The Normatec 3 is substantially equivalent to the predicate, NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169 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 3 Indications for Use and Contraindications are identical to the predicate NormaTec Pulse 2.0 and Pulse Pro 2.0 510(k) K183169.

Verification and Validation activities required that establish the performance, functionality, and reliability characteristics of the NormaTec Normatec 3 with respect to the predicate were performed. Testing performed demonstrated that the proposed device meets defined requirements and performance claims.

The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as the predicate device according to 807.92(b)(3).