July 14, 2022

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

Re: K221666
Trade/Device Name: Normatec Go
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 6, 2022
Received: June 8, 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)*
K221666

Device Name
Normatec Go

Indications for Use *(Describe)*
The Normatec Go 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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NormaTec Industries, LP

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Date of Preparation:	14-Jul-22
Official Contact:	Steve Henderson, Director of Quality & Regulatory Systems
Proprietary or Trade Name:	Normatec Go
Proposed Device:	Normatec Go
Common/Usual Name:	Massager, Powered Inflatable Tube
Classification Name	Powered inflatable tube massager
Regulation Number:	21 CFR 890.5650
Product Code:	IRP
Regulation Medical Specialty:	Physical Medicine
Predicate Device:	K220217 – Normatec 3
Secondary Predicate Device:	K213745 - Air Compression Therapy Device, model: ST-502, Shenzhen Future Electronic Co., Ltd
Classification Name	Powered inflatable tube massager
Common/Usual Name	Massager, Powered Inflatable Tube
Regulation Number:	21 CFR 890.5650
Product Code	IRP
Regulation Medical Specialty:	Physical Medicine

Device Description

The Normatec Go is a powered, inflatable tube, calf 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. The device is to be used by people who are in good health. The device is charged from an external compliant power supply and powered by an internal IEC 62133-2 compliant lithium-ion battery.

The user interface on the Normatec Go is a series of buttons with one small display screen, to display the treatment time, located on the control unit mounted on the calf wrap. 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 proposed device, the device also has Bluetooth capability that allows the use of the NormaTec app to control the device. The Normatec 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 Go 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

	Proposed New Device	Predicate Device	Secondary Predicate Device	Comment
Model Name 510(k) Number	Normatec Go 510(k) K221666	Normatec 3 510(k) K220217	Air Compression Therapy Device, model: ST-502 510(k) K213745	N/A
Manufacturer	NormaTec Industries, LP	NormaTec Industries, LP	Shenzhen Future Electronic Co., Ltd.	N/A
Prescriptive	OTC	OTC	OTC	Identical
Indications for use	The Normatec Go 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 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.	The Air Compression Therapy Device (model: ST-502) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device (model: ST-502) simulates kneading and stroking of tissues by using an inflatable garment.	The proposed and predicate device have identical Indications for Use. The secondary predicate device is included because the maximum pressure is similar to the proposed device. The difference between the proposed and secondary predicate device is the removal of “simulates kneading and stroking of tissues by using an inflatable garment.”
Anatomical Coverage	Control unit mounted to inflatable segment with integral hoses.	Not publicly available	Control unit connected to inflatable segments via a hose.	Proposed device is only for the leg
Method to secure the device to the extremity	The device is laid open and flat. Place device around calf, then secure by pulling tight until Velcro provides a snug fit against the calf.	Not publicly available	Place device around calf, then secure by pulling tight until Velcro holds.	The difference in method to secure the device in place does not raise any concerns or safety or effectives. Neither does it raise any new technological characteristics.

	Proposed New Device	Predicate Device	Secondary Predicate Device	Comment
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Similar
Power Source(s)	Charging via 5 VDC compliant power supply (100- 240 VAC input) Powered by Integrated rechargeable battery	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input) Integrated rechargeable battery	100-240V, 50-60Hz	Proposed device is not operational when plugged into the power supply.
Battery	Internal battery 3.6V, 2550mAh Internal battery (D610-1-d1-1S1P) 3.65V, 2600mAh	Internal battery 7.2 V, 3200mAh	Battery	Similar, but a smaller battery.
Software / Firmware Micro-processor Control	Microprocessor	Microprocessor	Microprocessor	Similar
Technology	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Consists of an air pump, air pressure sensor, leg sleeves and adapter.	Similar
Compliance with Voluntary standards	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 ANSI C63.27-2017	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 ANSI C63.27-2017	ANSI AAMI ES606011 :2005/(R)2012 and A1:2012, IEC 6060112 Edition 4.0 2014, ANSI AAMI HA 60601111:2015	Similar

	Proposed New Device	Predicate Device	Secondary Predicate Device	Comment
Performance Testing	V&V Summary Functional Verification Physical Features Verification Battery Drain Battery Charge System Air Release Battery Function Verification RF Pairing Verification	V&V Summary Functional Verification Physical Features Verification Battery Drain Battery Charge System Air Release Battery Function Verification	Not available	Performance Testing is identical, though the proposed device includes RF pairing testing.
Clinical Testing	None	None	None	Similar
Device Pressure Range	0 – 220 mm Hg	0 - 110 mm Hg	Up to 240 mm Hg	Increased pressure is within range of cleared secondary predicate device.
Pressure Levels	Level 1: 40 - 70 mm Hg max Level 2: 60 - 90 mm Hg max Level 3: 80 - 110 mm Hg max Level 4: 100 - 140 mm Hg max Level 5: 130 - 170 mm Hg max Level 6: 150 - 200 mm Hg max Level 7: 180 - 220 mm Hg max	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	Up to 240 mm Hg	Subject device has higher max pressure than the predicate, but the Secondary Predicate K213745 is up to 240 mmHg.
Treatment Time	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	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	20 mins	Similar

	Proposed New Device	Predicate Device	Secondary Predicate Device	Comment
Treatment Area	Calf	Leg, Arm, and Hip	Low limbs (Foot, calf, and upper leg)	The proposed device is intended for use only on the calf. The secondary predicate device has three (3) segments that can operate with all (foot, calf, and upper leg) or the user can activate only one segment (e.g., the calf)
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Sequential/Peristaltic	Similar
Contact Surface Material	200 denier nylon with a polyurethane aminate/extrusion	200 denier nylon with a polyurethane laminate/extrusion	Polyester	Similar
Number of Inflatable segments	3	5 or less	3	The proposed device is physically smaller and does not require more than 3 segments.
Weight	1.2 lbs	3.6 lbs	3.08 and 3.52 pounds	Similar
Dimensions (W x H x D)	4.94” x 1.27” x 2.76”	4.17” x 3.66” x 8.25”	L215mm x W65mm x H51mm	Similar
Materials	Wrap– nylon / polyester Velcro Controller housing Molded ABS enclosure (94V0)	Not publicly available	Sleeve – nylon / polyester Velcro Controller housing Molded ABS enclosure (94V0)	Similar
Patient contact	Non-conductive nylon containing air bladders that when secured around the calf by Velcro, form zones of air tubes for compression.	Non-conductive appliances	Non-conductive attachments	Similar

Determination of Substantial Equivalence

The Normatec Go is substantially equivalent to currently marketed and cleared devices (K220217) because:

Indications for Use
The Normatec Go indications for use are identical to the predicate, Normatec 3, 510(k) K220217.

Prescriptive
The Normatec Go and the predicate Normatec 3 (K220217) and secondary predicate device (K213745) are OTC devices.

Design, Technology, and Principle of Operation
The Normatec Go has equivalent design and features, and similar technology to the predicate, Normatec 3, 510(k) K220217.

Design and Technology
The proposed device Normatec Go differs in design from the predicate Normatec 3 (K220217) in the following ways:

- Normatec Go has a rechargeable battery that allows the user to operate the device without requiring the device to be connected to power like the predicate Normatec 3 (K220217). Normatec Go will not operate while the device is connected to power and charging the battery.
- The control unit or Display Screen – which includes the Start/Stop button, Time Adjustment button, and Pressure Adjustment button – is attached directly to Normatec Go.
- The air hoses for the proposed device Normatec Go are contained within the device. The air tubes have been relocated in a service pouch to improve the aesthetic look of the device, though they are still directly connected to the control unit. For the predicate device Normatec 3 (K220217), one air hose protruded from the leg, arm, or hip appliance to connect directly to the control unit.

Method to Secure the Device
The proposed device is unfolded, then wrapped around the calf until snug. The proposed device has Velcro to ensure the device is secure and snug prior to starting treatment.

Principle of Operation
The Principle of Operation for the proposed device Normatec Go, predicate device Normatec 3 (K220217), and secondary predicate device – Air Compression Therapy Device (K213745) is identical.

Maximum Pressure
The subject device is capable of reaching up to 220 mm Hg.
The predicate device is capable of reaching up to 110 mmHg. The secondary predicate device is capable of reaching up to 240 mm Hg.

Though the maximum pressure for the proposed device Normatec Go exceeds the maximum pressure for

the predicate device Normatec 3 (K220217), we have included a secondary predicate device with similar technology, principle of operation, and indications for use that has a maximum pressure of 20 mm Hg higher than the Normatec Go. While this pressure is higher than the predicate device Normatec 3 (K220217), this higher pressure does not raise any different safety or effectiveness concerns for the subject device Normatec Go.

Treatment Area

The proposed device Normatec Go is offered as a calf only device.

The predicate device Normatec 3 (K220217) had three models: leg, arm, and hip. While the treatment areas of the body may differ, the fundamental technology and method of treatment is identical.

The secondary predicate device Air Compression Therapy Device (K213745) can treat the foot, calf, and upper leg simultaneously or each zone independently. When operated to one specific area (i.e., calf), this is similar to the proposed device Normatec Go, which is limited to the calf only. We do not believe that treatment of only the calf muscle raises any new safety or effectiveness concerns for the proposed device Normatec Go.

Bluetooth and Smartphone Application

Both the proposed device Normatec Go and the predicate Normatec 3 have identical Bluetooth capability that allow both devices to connect to the NormaTec app. Our app is compatible with both iOS and Android platforms. The app is the identical for both the predicate Normatec 3 and the proposed Normatec Go. The user can adjust the pressure level, time and the starting and stopping of the session. The app has the same functionality as the device. The app acts like a remote control for users who do not want to use the controls located on the device.

Battery

Normatec Go passed testing with a different, smaller battery due to the size of the control unit – the size of the control unit Normatec Go is smaller than the predicate device Normatec 3 (K220217).

Performance and Specifications

The Normatec Go has equivalent specifications of performance when compared to the predicate, Normatec 3, 510(k) K220217 except for the maximum pressure. We have compared to the secondary predicate device K213745 which has similar maximum pressure limits.

Compliance with Standards

Both devices have been tested with AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11 and ANSI C63.27-2017 and passed the acceptance criteria.

Patient Contacting Materials

The patient-contacting materials of the Normatec Go are identical to the predicate Normatec 3 (K220217).

Intended Use Environment

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

Features

The Normatec Go has equivalent features when compared to the predicate Normatec 3 (K220217).

Performance Testing
The Normatec Go underwent identical performance testing to the predicate Normatec 3 (K220217) with the inclusion of RF pairing testing. The testing included Software V&V, Functional Verification Physical Features Verification, Battery Drain, Battery Charge, System Air Release, Battery Function Verification and RF Pairing Verification. The subject device met all acceptance criteria.

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

Animal testing
There was no animal testing.

Clinical Testing
There was no clinical testing.

Conclusion
The Normatec Go is substantially equivalent to the predicate Normatec 3 (K220217) in:

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

The 510(k) summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that the device is substantially equivalent as compared to the predicate device according to 807.92(b)(3).