September 18, 2025

NormaTec Industries, LP
℅ Matt Dryden
Director
ProMedic, LLC
131 Bay Point Drive NE
St. Petersburg, Florida 33704

Re: K251905
Trade/Device Name: Normatec Elite Hip
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 21, 2025
Received: August 21, 2025

Dear Matt Dryden:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251905

Please provide the device trade name(s).

Normatec Elite Hip

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

NormaTec Industries, LP

Date of Preparation:	June 20, 2025
480 Pleasant Street Suite A200 Watertown MA 02472	Tel – 800.355.0960 Fax – 866.279.2579
Sponsor Contact:	Steve Henderson, Director of Quality & Regulatory Systems
Submission Correspondent:	Matt Dryden, Esq. (ProMedic, LLC)
Proprietary or Trade Name:	Normatec Elite Hip
Subject Device:	Normatec Elite Hip
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:	K240122 – Normatec Elite
Classification Name	Powered inflatable tube massager
Common/Usual Name	Powered inflatable tube massager
Regulation Number:	21 CFR 890.5650
Product Code	IRP
Reference Device:	K220217 – Normatec 3
Classification Name	Powered inflatable tube massager
Common/Usual Name	Powered inflatable tube massager
Regulation Number:	21 CFR 890.5650
Product Code	IRP

Device Description

The Normatec Elite Hip 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 charged and powered from an external compliant power supply. In addition, powered by an internal IEC 62133-2 compliant lithium-ion battery.

The user interface on the Normatec Elite Hip is a series of buttons with a small display screen to display the treatment time, pressure level, zone boost number. The user interface provides for:

- Starting and stopping the massage treatment;
- Adjusting time and intensity (pressure) of the treatment;
- Selection of the zone to boost the pressure

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 Elite Hip 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 Device Normatec Elite Hip	**Predicate Device Normatec Elite – K240122**	**Reference Device Normatec 3 - K220217**	**Comment**
Manufacturer	NormaTec Industries, LP	NormaTec Industries, LP	NormaTec Industries, LP	
Prescriptive	OTC	OTC	OTC	Identical
Indications for use	The Normatec Elite Hip 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 Elite 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 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.	Identical
Anatomical Coverage	Control unit mounted to inflatable segments with integral hoses. 	Control unit mounted to inflatable segments with integral hoses. 	Control unit connected to hip attachment via hose. 	Identical Normatec 3 – K220217 is listed as a reference device because it includes a hip attachment, which was not included in Normatec Elite – K240122.
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical

	Proposed Device Normatec Elite Hip	Predicate Device Normatec Elite – K240122	Reference Device Normatec 3 - K220217	Comment
Power Source(s)	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Integrated rechargeable battery	12 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input) Integrated rechargeable battery	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC input) Integrated rechargeable battery	Identical
Software / Firmware Micro-processor Control	Microprocessor	Microprocessor	Microprocessor	Identical
Technology	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Identical
Compliance with Voluntary standards	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and ANSI C63.27-2017	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and ANSI C63.27-2017	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and ANSI C63.27-2017	Identical
Device Pressure range	0 - 110 mm Hg	0 - 110 mm Hg	0 - 110 mm Hg	Identical
Pressure Levels	Level 1: 40 mm Hg Level 2: 50 - 60 mm Hg Level 3: 60 - 70 mm Hg Level 4: 70 - 80 mm Hg Level 5: 80 mm Hg Level 6: 80 - 90 mm Hg Level 7: 100 mm Hg	Level 1: 40 mm Hg Level 2: 50 - 60 mm Hg Level 3: 60 - 70 mm Hg Level 4: 70 - 80 mm Hg Level 5: 80 mm Hg Level 6: 80 - 90 mm Hg Level 7: 100 mm Hg	Level 1: 40 mm Hg Level 2: 50 - 60 mm Hg Level 3: 60 - 70 mm Hg Level 4: 70 - 80 mm Hg Level 5: 80 mm Hg Level 6: 80 - 90 mm Hg Level 7: 100 mm Hg	Identical
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	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.	Identical

	Proposed Device **Normatec Elite Hip**	**Predicate Device** **Normatec Elite – K240122**	**Reference Device** **Normatec 3 - K220217**	**Comment**
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Identical
Contact Surface Material	200 denier nylon with a polyurethane laminate/extrusion	200 denier nylon with a polyurethane laminate/extrusion	200 denier nylon with a polyurethane laminate/extrusion	Identical
Number of Inflatable segments	2 segments for Hip attachment *Hip attachment only	5 segments for leg attachment *Leg attachment only	5 segments for leg attachment 2 segments for hip attachment 5 segments for arm attachment	Different Normatec 3 – K220217 is listed as a reference because it includes a similar hip attachment, which utilizes similar technology.
Weight	3.0 lbs	3.0 lbs	3.6 lbs	Identical
Control Unit Dimensions (W x H x D)	3.5” x 1.75” x 7.0”	3.5” x 1.75” x 7.0”	4.17” x 3.66” x 8.25”	Identical
Housing Materials and Construction	Molded ABS enclosure (94V0)	Molded ABS enclosure (94V0)	Molded ABS enclosure (94V0)	Identical
Patient contact	Non-conductive wrap Surface Device Intact Skin Limited Duration (<24 hours)	Non-conductive wrap Surface Device Intact Skin Limited Duration (<24 hours)	Non-conductive wrap Surface Device Intact Skin Limited Duration (<24 hours)	Identical

Differences Between Models

An "X" indicates the feature is present in the device.

Characteristic	Normatec Elite	Normatec 3
Power On – The system has settings for:		
Adjustable Treatment time (15 min to 60 min)	X	X
5 Zone Inflatable Leg Boot		X
2 zone Inflatable Hip Sleeve	X	
7 Pressure Levels	X	X
Time		
User can Add time Before treatment During treatment	X	X
User can Decrease time Before treatment During treatment	X	X
Provides a Counter	X	X
Count down – 1 second increments	X	X
Compliance – Trip meter	X	X
Chronometer Odometer – cannot be reset by User	X	X
Pressure		
User can Increase level Before treatment During treatment	X	X
User can Decrease level Before treatment During treatment	X	X

Characteristic	Normatec Elite	Normatec 3
Treatment Mode		
NormaTec Patented Pulse Algorithm	X	X
Treatment		
Starting via button press	X	X
Pause via button press	X	X
Un-pause via button press	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		
Control unit interface displays battery level	X	X
Control unit interface displays when battery is charging	X	X
Power On/Off Button		
Off mode - No treatment in process	X	X
On mode - Treatment is process when start button also pressed.	X	X

Differences between Proposed and Predicate Device Discussion

The subject device differs in the following ways from the predicate:

- The subject device contains a hip attachment only, which was not included in the predicate – Normatec Elite – K240122 (leg only).
    - The reference device Normatec 3 – K220217 includes a similar hip attachment, which utilizes similar technology and identical Indications for Use.
- Predicate – Normatec Elite Software / Firmware was revised to:
    - Disable RF for synchronous functionality
    - Alter solenoid algorithm for 2 segments instead of 5.
    - There were no other changes to the software / firmware.
    - We have provided a table above outlining the similarities and differences between the subject and predicate device.

Discussion of Differences

The software was modified in the following ways: disable RF for synchronous functionality, and altered solenoid algorithm for 2 segments instead of 5. The same software function was previously cleared in the predicate device – Normatec Elite – K240122.

The hip attachment is not a new technology or anatomical location for NormaTec devices. FDA has been previously reviewed and cleared a similar hip attachment under Normatec 3 – K220217.

The differences between the subject and predicate device do not raise any new concerns regarding the safety and effectiveness as demonstrated by performance testing.

Substantial Equivalence Discussion

Substantial Equivalence Discussion
The table above compares the key features of the proposed device with the identified predicate – Normatec Elite – K240122. The comparison demonstrates that the proposed device can be found to be substantially equivalent to the predicate device.

Indications for Use –
The indications for use are identical for the subject device when compared to the predicate device.
Discussion – The subject and predicate device have identical Indications for Use.

Technology and construction –
The technology and principle of operation is similar for the subject device when compared to the predicate device.
Discussion – Subject device operation is made to fit the hip, while the predicate device operation is made to fit the leg. We have included a NormaTec device as a reference device demonstrating that FDA has previously cleared a similar device with similar technology and construction. The subject device design has changed, but the principle of operation remains similar. The performance metrics are consistent between the subject, predicate, and reference devices.

Environment of Use –
The environments of use are identical, which are clinics, hospital, athlete training, and home environments.
Discussion – The environments of use are identical for the subject and predicate devices.

Patient Population –
The patient population is adults.
Discussion – The subject and predicate device patient populations are identical.

Non-Clinical Testing Summary –

Bench testing –
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

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

Discussion – The test results are similar to the predicate and within pre-defined acceptance criteria.

Biocompatibility –
The materials utilized in the subject device are identical to the listed predicate as they were approved in their respective 510(k)s and their relationship to the patient for the proposed device are identical in formation, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.)
Discussion – The subject device was found to meet the applicable requirements for biocompatibility safety for the

intended population.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and non-clinical testing that the subject device and predicate have been found to be substantially equivalent.