November 4, 2022

Aquilo Sports LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223164
Trade/Device Name: Aquilo Sports CCT1500 System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: October 06, 2022
Received: October 07, 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,

Vivek Pinto, PhD
Director
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)*
K223164

Device Name
Aquilo Sports CCT1500 System

Indications for Use *(Describe)*
The Aquilo Sports CCT1500 System 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 CCT1500 simulates kneading and stroking of tissues by using an inflatable garment.

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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K223164

Date Prepared:	November 2, 2022
Applicant	Aquilo Sports 1902 Campus Pl Ste 12 Louisville, KY 40299 Tel – 502 290 8994
Official Contact:	John Paul Spence VP Sales and Marketing
Proprietary or Trade Name:	Aquilo Sports CCT1500 System
Common/Usual Name:	Powered Inflatable Tube Massager
Classification Name:	IRP - Massager Powered Inflatable Tube (CFR 890.5650)
Predicate Device:	IRP Rapid Reboot 510(k) K182668
Reference Device:	NormaTec Pulse and NormaTec Pulse Pro 510(k) K160608:

Device Description:
This submission is for the Aquilo Sports CCT1500 System is a powered inflatable tube massager. It is being submitted as an over the counter device.

The device 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 CCT1500 simulates kneading and stroking of tissues by using an inflatable garment.

The device is a Class II, type BF applied part that receives power a separately approved external IEC 60601-1 compliant power supply or integral battery pack.

The CCT1500 consists of an air compressor unit with a control system, an inflatable "boot" for the leg, plastic air tubing with a proprietary connector for connecting the device to the boot.

The user interface is a front panel display and buttons.

The CCT1500 contains an air compressor with a system control that that allows the user to adjust the amount of air coming from the air compressor and going to the individual segments of the inflatable boot.

There is no electrical contact with the user and the device does not transfer or detect energy to or from the user.

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The user interface of the CCT1500 provides for starting and stopping the massage treatment, allows for adjusting time and intensity (pressure) of the treatment. The device also provides a proprietary keyed connector to the tubing which connects to the boot.

Pressure level is selectable between 20 and 150 mmHg

Indications for Use:
The Aquilo Sports CCT1500 System 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 CCT1500 simulates kneading and stroking of tissues by using an inflatable garment.

Patient Population:
Adults

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

510(k) Summary

Table of the Similarities and Differences of Predicate vs. Proposed Device Over The Counter Device

Model Name **510(k) Number**	**New Device** **Aquilo Sports CCT1500 System**	**Predicate Device** **Rapid Reboot** **510(k) K182668**	**Comment**
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Identical
Indications for use	The Aquilo Sports CCT1500 System 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 CCT1500 simulates kneading and stroking of tissues by using an inflatable garment.	The Rapid Reboot Compression Therapy System 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 Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Identical
OTC or Prescription	OTC	OTC	Identical
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Compliance with Voluntary standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2	The CCT1500 meets home use standard
Mode of Operation	Sequential	Sequential/Peristaltic	No difference. Peristaltic and Sequential are synonymous

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Cycle Time	Between 8 sec. and 95 sec. (full cycle - including hold time) depending on device settings*.	1 min 20 sec	Similar
Hold Time	Between 4 sec. and 95 sec. depending on device settings*.	Not available	Similar
Power	100-240 V, 50-60 Hz, 2.5A Max Internal rechargeable battery	110 V, 60Hz	The addition of the battery does not impact the efficacy of the device. The device and battery have been tested for safety to current standards
Device Pressure range	20-150mmHg	0 - 200 mmHg	The CCT1500 has a more restricted range
Treatment Time	Treatment time programmable from 20-150 minutes in 5-minute intervals. Time default is 30 minutes	User determines therapy time. Choose from 10, 20, or 30 minutes session time, with option to add additional 10 minutes to any therapy time.	Maximum selectable time is 200 minutes which is longer that the predicate but shorter than the reference device as below
Garments contact surface Material	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Same materials
Leg Attachment	Yes	Yes	Identical in size and construction
Number of Inflatable appliance Segments	6	4	Similar.
Weight	18.1 pounds	5.8 pounds	Similar. CCT1500 weighs more in part because of battery
Dimensions (W x H x D)	16” x 8.25” x 10.25”	10” x 6.5” x 5”	Similar

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Housing Materials and Constructions	Molded ABS enclosure	Molded ABS enclosure	Identical
Patient contact	Non-conductive appliances	Non-conductive appliances	Identical
Safety Features	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Identical
Modes	5 modes, sequential and uniform (all segments inflated deflated at once).	2 Modes: "A" mode inflates and deflates chambers from bottom to up (distal to proximal chambers), one at a time "B" mode also inflates from bottom up, but maintains pressure in lower chambers as it works it way to the top. Then all chambers release pressure at the same time once all chambers have sequentially inflated	Similar
Accessories	One size Length: 36" Max Width: 27"	X-Short: 14" x 41" Short: 14" x 43" Medium: 14" x 45" Long: 14" x 48" X-Long: 14" x 52"	CCT1500 only offers leg attachment
SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Identical
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Identical

*The cycle time and hold time of the device are contingent on the settings programmed by the user. These times will fluctuate within the described range depending on the user's input for the pressure, active chambers, and compression mode settings. For example, using only one compression chamber at a low pressure will result in cycle and hold times on the low end of the range, while using all six chambers at a high pressure will result

in cycle and hold times at the upper end of the range. Additionally, the hold time will be different for different chambers in the compression boot during sequential compression. In compression mode 1, compression chamber 1 at the foot will inflate and maintain the target pressure while the rest of the boot inflates, meaning the hold time in chamber 1 will be maximized (up to 95 seconds), while the hold time in chamber 6 will be minimized (4 seconds).

Reference Device: NormaTec Pulse and NormaTec Pulse Pro 510(k) K160608:

The NormaTec Pulse and NormaTec Pulse Pro are used as a reference device for "Treatment Time". The subject device has a treatment time of 20-150 minutes in 5-minute intervals. Time default is 30 minutes while the reference device is user controlled 10 minutes to 175 minutes or continuous. As the reference device includes a continuous treatment time setting, we maintain that the subject device range is within the reference.

510(k) Summary

Substantial Equivalence Discussion

In the above tables we have compared the CCT1500 to the predicate for equivalence of:

Indications –

The Aquilo Sports CCT1500 System 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 CCT1500 simulates kneading and stroking of tissues by using an inflatable garment.

These indications are identical to the predicate device.

Design, Technology and Principle of Operation – The CCT15000 is equivalent in design and features when compared to the predicate and has identical technology

Performance and Specifications – The CCT1500 has equivalent specifications of performance when compared to the predicate device. This includes cycle time and hold time.

Compliance with standards – The CCT1500 is compliance with IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 which is identical to the predicate devices.

Patient Population –

The CCT1500 and predicate are indicated for adults

Environment of Use –

The CCT1500 environments are identical to the predicate

Differences –

There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

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 performance

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: 2014, Collateral standard: Electromagnetic Disturbances - Requirements and Tests

- IEC 60601-1-11: 2015, 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

Differences –
There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

Substantial Equivalence Rationale

The CCT1500 is viewed as similar to the predicate device because:

Indications – are identical to the predicate

Prescriptive – The CCT1500 is over the counter and same as the identified predicate.

Design, Technology and Principle of Operation – The CCT1500 has equivalent design and features when compared to the predicate and has the identical technology.

Performance and Specifications – The CCT1500 has equivalent specifications of performance when compared to the predicate.

Compliance with standards – The CCT1500 declares compliance with IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 which is identical to the predicate.

Environment of Use – Identical to the predicate.

Features - The CCT1500 has equivalent features when compared to the predicate device

Conclusion

510(k) Summary

The CCT1500 is similar to the predicate in: indications for use, 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. Therefore, subject device is substantially equivalent to the predicate device.