February 6, 2025

TermoSalud
% Aubrey Thompson
Regulatory Consultant
Hoy and Associates Regulatory Consultants
1830 Bonnie Way
Sacramento, California 95825

Re: K243488
Trade/Device Name: Vmat Pro
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic Massager
Regulatory Class: Class I
Product Code: ISA
Dated: October 31, 2024
Received: November 12, 2024

Dear Aubrey Thompson:

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,

Heather L. Dean -S

for Amber Ballard, PhD
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243488

Device Name

VMAT PRO

Indications for Use *(Describe)*

The VMAP PRO is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue.

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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510(K) Summary
VMAT PRO K243488

Applicant	TermoSalud
Address	Ataulfo Friera Tarfe, 8 -33211 Gijón, Spain
Applicant Contact	Cristina Cifuentes Pantoja
Correspondent Contact	Aubrey Thompson, Regulatory Consultant AubreyThompson@hoyregulatory.com
Preparation Date	February 6, 2025
Device Trade Name	VMAT PRO (K243488)
Device Classification Name	Massager, Therapeutic, Electric
Common Name	Therapeutic electric massager
Regulation Number	21 CFR 890.5660
Product Code	ISA
Regulatory Class	I
Legally Marketed Predicate Device	D-Actor 200 Vibration Massage System (K173692)

Device Description:
The VMAT PRO is a pressure pulse device that creates pneumatically generated pressure pulses caused by compressed air delivering ballistic projectile through a handpiece coming into contact with the skin. VMAT PRO is equipped with one handpieces that includes four transmitters [VAT120 (diameter of 20mm), VAT220 (diameter of 20mm), VAT215 (diameter of 15mm), and VAT 135 (diameter 35mm)] that allow radial treatments, ergonomically designed to allow the user to work in various areas of the body.
To facilitate the movement of the transmitter on the skin, and guarantee a correct contact, an ultra-sound gel FDA cleared should be used (i.e. Aquasonic 100 Ultrasound Transmission Gel K802146).

Indications for use:
The VMAT PRO is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation, and activation of connective tissue.

Substantial Equivalence—Technological Characteristics:

Subject Device	Predicate Device	Comparison
The VMAT PRO is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation, and activation of connective tissue	The D-ACTOR® 200 Vibration Massage System is intended for: Relief of minor muscle aches and pains, temporary increase in local blood circulation, activation of connective tissue	Identical.

Technical Comparison	VMAT PRO	**D-ACTOR® 200 Vibration Massage System (K173692)**	**Comparison**
Modes of action	HP-AT pressure pulse handpiece	Radial pressure waves, or extracorporeal pulse activation respectively	Same
Mechanism of action	Pneumatically generated vibrations	Pneumatically generated vibrations	Same
Type of acoustic wave generation	Pneumatic/ballistic	Pneumatic/ballistic	Same
Pulse repeat rate (1/s)	1-21 Hz	1-21Hz	Same
Maximum and Minimum intensity setting	0.5-5.0 bar	1-5 bar	Very similar- the pressure on the VMAT PRO goes slightly lower than the predicate device, but it does not impact the safety of the device. Treatment pressure is adjusted for patient comfort, so a slightly lower pressure can be more comfortable for patients.
Type of application	Continuous vibration at a fixed frequency	Continuous vibration at a fixed frequency	Same
Driving power	1-5 bar	1-5 bar	Same
Projectile Mass (g)	3.1 g	3g	Same
Pulse repeat rate	1-21Hz	1-21Hz	Same
Number of pulses	Variable	variable	Same

Max and Min displacement of applicator heads	VAT220: Max: 1.230 mm Min: 0.350 mm VAT215: Max: 0.320 mm Min: 0.120 mm VAT120: Max: 1.300 mm Min: 0.700 mm VAT 135: Max: 0.760 mm Min: 0.300 mm	0.6 – 2.0 mm	Different. There are different ways of measuring this variable and that not all of them are equally accurate. In our case, it has been measured in a laboratory, using ultrasound. The difference in values is minimal and does not pose a risk to the safety of the equipment and the user.
Pressure	0.5-5.0 bar (7.25 psi - 72.5psi)	1-5 bar	Very similar- the pressure on the VMAT PRO goes slightly lower than the predicate device, but it does not impact the safety of the device. Treatment pressure is adjusted for patient comfort, so a slightly lower pressure can be more comfortable for patients.
Beam Pressure Maximum (BPM)	**According to IEC 63045 (at 5 bar)**	**According to modified protocols from IEC 61846**	The measurements taken are different
	VAT 220: 45.8 mJ VAT 215: 34 mJ	N/A	

	VAT 120: 24 mJ VAT 135: 34 mJ		

Total Derived focal acoustic pulse energy	N/A	5bar/6.5mJ 3bar/2.4mJ	because the measurement for the acoustic pulse was conducted per IEC 63045 standards, which requires Beam Pressure Maximum measurements. The energy values of the VMAT PRO are well within the usual range for pressure pulse devices. the difference between the values of our VMAT PRO and the values of D-Actor 200 is due to the terms used in the standard. See further explanation of the difference in specifications below.
Positive derived acoustic pulse energy	**According to IEC 63045 (measured for VAT220 at 5bar)** VAT 220: 39.9 mJ VAT 215: 23 mJ VAT 120: 17 mJ VAT 135: 32 mJ		
Positive peak pressure	VAT220: 5 bar: 8.1 MPa 3 bar: 6.7 MPa VAT215:	Values of ultrasonic pulse: 5bar/18.5MPa 3bar/13.4MPa	The difference in these values is due to difference in testing methodology. See discussion below.

	5 bar: 11.3 MPa 3 bar: 8.1 MPa VAT120: 5 bar: 6.3 MPa 3 bar: 4.9 MPa VAT 135: 5 bar: 3.8 MPa 3 bar: 2.8 MPa		
Negative peak pressure	VAT220: 5 bar: 6.5 MPa 3 bar: 5.1 MPa VAT215: 5 bar: 3.6 MPa 3 bar: 2.8 MPa VAT120: 5 bar: 5.8 MPa 3 bar: 5.4 MPa VAT 135: 5 bar: 2.5 MPa 3 bar: 2.2 MPa	Values of ultrasonic pulse: 5bar: 6.8MPa 3bar: 5.0MPa	Same as VAT220. The 510K summary of the predicate device does not state which transmitter was tested for these values.
Derived pulse-intensity integral (Energy Flux Density)	VAT220: 5 bar: 0.267 mJ/mm2 3 bar: 0.152 mJ/mm2 VAT215: 5 bar: 0.224 mJ/mm2 3 bar: 0.135 mJ/mm2	Values of ultrasonic pulse according to modified protocols from IEC 61846: 5bar: .284 mJ/mm2 3bar: .176 mJ/mm2	Different. While the values are not identical, they are very close in to one another for the VAT220 and the remaining transmitters all have

	VAT120: 5 bar: 0.252 mJ/mm2 3 bar: 0.187 mJ/mm2 VAT 135: 5 bar: 0.207 mJ/mm2 3 bar: 0.129 mJ/mm2		lower values than they predicate.
Maximum penetration depth	VAT 220: 33.1 mm VAT 215: 23.1 mm VAT 120: 32 mm VAT 135: 35 mm	32.3mm	Different. The differences are within 1 mm of the predicates, which does not impact the safety or efficacy.
Working mode	Continuous	Continuous	Same
Rise time (measured at 5bar (10%-90%) (µs)	VAT220 Ultrasonic pulse: 4.97 µs VAT215	Ultrasonic pulse: 2.5 µs	Similar. These rise times are all within the standard range for pressure pulse devices.

	Ultrasonic pulse: 2.41 µs VAT 120: Ultrasonic pulse: 4.28 µs VAT 135: Ultrasonic pulse: 4.16 µs		See further discussion below.
Compressional pulse duration (measured at 5 bar in µs)	VAT220 Ultrasonic pulse: 6.6 µs VAT215 Ultrasonic pulse: 2.93 µs VAT120: Ultrasonic pulse: 4.78 µs VAT 135: Ultrasonic pulse: 6.96 µs	Ultrasonic pulse: 5 µs	Similar. These pulse durations are all within the standard range for pressure pulse devices. See further discussion below.
Power Supply	230 VAC 50 Hz 115 VAC 60 Hz (optional with reference M93AF)	500 VA	
Maximum operating Temperature	18-30C	10-40c	The VMAT operating temperature is within the range of the predicate's
Treatment heads	4: 20mm, 20mm, 35mm, 15mm	4: 6mmOD, 15mmOD, 20mmOD, 35mmOD	Similar sizes
Patient Contacting Materials	Titanium, Stainless Steel, Polyoxymethylene	Steel	Similar for transmitters, different for transmitter casing.

Performance Testing
Verification and validation activities were successfully completed and establish that the VMAT PRO control unit performs as intended. Testing included the following:

IEC 60601-1:2005 (Third Edition) + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests

IEC 63045:2020 Ultrasonics -Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields.

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Biocompatibility
All tissue contacting materials were tested for biocompatibility according to ISO 10993-1:2018 and found to be biocompatible.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Substantial Equivalence Discussion

Though the measurements in the substantial equivalence table above shows some differences between the VMAT PRO and the predicate device, the differences are due to different measuring methods. A key parameter to compare is the derived pulse-intensity integral (energy flux density, measured in mJ/mm^2). This parameter demonstrates efficacy because the therapeutic effectiveness of pressure pulses depends on whether the energy of the pressure pulse is distributed over a large area or focused on a locally confined treatment zone (focal zone). The measure of energy concentration is obtained by calculating the energy per area (derived pulse-intensity integral) and is obtained after the pulse has stabilized, not at the first impulse or shot.

Test Methods

The performance testing for the predicate device was conducted using modified protocols from the IEC 61846 standard. Testing for the VMAT Pro was conducted to the standard IEC 63045. This resulted in several differences in the measurements taken.

Devices such as the VMAT PRO do not have a focus, so the term *derived focal acoustic pulse energy* is not applicable in this case. The term is also not used in IEC 63045. In IEC 63045, the focus has been replaced by the beam pressure maximum (BPM).

The derived pulse-intensity integral values of the VMAT PRO are within the usual range for pneumatic pressure pulse devices. Therefore, the difference between the values of our VMAT PRO and the values of D-Actor 200 is due to the terms used in the regulations.

Conclusion

The VMAT PRO and D-Actor 200 are identical in their indications for use and similar in their overall design. The key specification to compare, the derived pulse-intensity integral, is nearly identical between the devices. Differences that exist are due to either differences in the method of pressure wave generation, or differences in the test methods used. The differences do not impact the safety or efficacy of the VMAT PRO device and the key comparisons show that the VMAT PRO is substantially equivalent to the predicate device.