November 5, 2025

ViaTherm Therapeutics, LLC
℅ Sharon Bishop
Director, Regulatory Affairs
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
St. Louis, Missouri 63011

Re: K250376
Trade/Device Name: ViVY
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: October 6, 2025
Received: October 6, 2025

Dear Sharon Bishop:

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,

Amber T. Ballard -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250376

Device Name
VIVY™

Indications for Use *(Describe)*
The VIVY™ is to be used to generate deep heat within body tissues for the treatment of medical conditions such as relief of pain and muscle spasms.

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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ViaTherm ViVY™ 510(k) Summary

Submitter's information

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Pittsburgh, PA 15222

Contact: Sharon Bishop
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
Ballwin, MO 63011
Phone: 919-724-8978
Date: November 5, 2025

Classification

The classification for the new device is listed below.

21 CFR Reference	Product Code	Class	Generic Device Name	Classification Description
§890.5290	IMJ	II	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat	Shortwave diathermy

New device

The new device's indications for use are listed in the table below.

Device Name	Indications for Use
Vivy™	The Vivy is to be used to generate deep heat within body tissues for the treatment of medical conditions such as relief of pain and muscle spasms.

Predicate device

The predicate device for the Vivy is shown in the table below.

K Number	Product Code	Predicate Device Name	Indications for Use
K173300	IMJ	ViaTherm BOOST Diathermy System	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.

ViaTherm ViVY™ 510(k) Summary, Continued

Device description

The Vivy is used for diathermic heating of tissue. It consists of a compact, low-power, radio frequency (RF) generator contained within a garment to deliver therapeutic warming to injured tissues to facilitate the healing process. The power level and treatment time are adjustable. The device treatment is intended to be self-administered in the home.

Electronic circuitry in the power generator components generates a radiofrequency (RF) signal at a frequency of 13.56 Megahertz (MHz). The radiofrequency signal is delivered to the heat applicator garment that uses induction coil (magnetic field) technology to produce electromagnetic fields external to the applicator. This energy is converted into heat by electromagnetically resistant body tissues. Continuous shortwave diathermy (CSWD) with the ViaTherm Vivy System produces therapeutic warming from within the tissues

The power generator consists of a battery pack, voltage regulators, a power control and analog sensor module, and an RF generator. A shielded cable with 50 Ohms impedance connects the power generator to the heat applicator garment. The electrode consists of two flat spirals incorporated into the applicator garment. The spirals are each tuned to 50 Ohms. The power from the generator is split and sent to the two spirals, one of which is driven 180 degrees out of phase from the other.

The Vivy contains the following components:

- Rechargeable power generator containing a battery pack, regulator, power control, and analog sensor module
- Garment belt
- Heat applicator with dual RF coils
- USB cable
- Garment cable

ViaTherm ViVY™ 510(k) Summary, Continued

Characteristics The table below lists the attributes and characteristics for the new and predicate.

Attribute	New Device ViaTherm ViVy System	Proposed Predicate ViaTherm BOOST K173300
Intended Use/ Indications For Use	The Vivy is to be used to generate deep heat within body tissues for the treatment of medical conditions such as relief of pain and muscle spasms.	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.
Trade/Device Name	Vivy	ViaTherm BOOST System
Regulation Number	21 CFR 890.5290	21 CFR 890.5290
Regulation Name	Shortwave Diathermy Device	Shortwave Diathermy Device
Product Code	IMJ	IMJ
Target Population	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or over-training.	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or over-training.
Intended Environment For Use	OTC device intended for use by patients in non-clinical environments, including the home	OTC device intended for use by patients in non-clinical environments, including the home
Design	User-friendly device designed with safety mechanisms that enable it to	User-friendly device designed with safety mechanisms that enable it to

Attribute	New Device ViaTherm ViVy System	Proposed Predicate ViaTherm BOOST K173300
	be effectively and safely operated by a non-technical adult in non-clinical environments, including the home setting.	be effectively and safely operated by a non-technical adult in non-clinical environments, including the home setting.
Mechanism of Action	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents
Anatomical Site Locations	Multi-use therapy garment for target location areas: Arm, back, shoulder, leg, foot. Initial release for lower back garment.	Multi-use therapy garment for target location areas of 5 to 18 square inches: Arm (e.g. bicep, wrist, forearm), back, shoulder, leg (e.g. thigh, knee, calf), foot.
Treatment time	Software selection 45 minutes	40 minutes
Available Warming Control	Software selection 0, 50, and 100%	Single setting. Not adjusted by patient.
Thermal performance	Achieves 4°C temperature rise at 40 minutes	Achieves 4°C temperature rise at 25 minutes
Materials	Rechargeable power generator Heat applicator with dual RF coils USB cable Garment cable Charge adapter Garment Belt Material: • Wrap Lock by BeoCare, a Nylon and polyester blend medical grade fabric • Texacro™ Velcro fastener	Generator Charger Cord Therapy Garment Material: • Futuro™ by 3M, composed of polyurethane foam, nylon, polyester, polyethylene, and spandex • Velcro Extender Strap Patient Interface – 100% cotton pad
Safety Factors	The device treatment is intended to be self-administered in the home. The device is battery operated. It	The device treatment is intended to be self-administered in the home. The device is battery

Attribute	New Device ViaTherm ViVy System	Proposed Predicate ViaTherm BOOST K173300
	contains circuit boards that determine if the garment is making sufficient contact with the user, and if so, will output the designated power. The treatment time is based on the life of the battery, preventing the user from over treating.	operated. It contains circuit boards that determine if the garment is making sufficient contact with the user, and if so, will output the designated power. The treatment time is based on the life of the battery, preventing the user from over treating.
Use environment	Designed for OTC use by a non-technical person	Designed for OTC use by a non-technical person
Operating Frequency	13.56 MHz	13.56 MHz
RF Power	10 watts	5 watts
Duty Cycle	Continuous Wave	Continuous Wave
RF Connector	BNC	BNC
Impedance	50 Ohms nominal	50 Ohms nominal
Load Standing Wave Ratio	3.0:1 max	3.0:1 max
Batteries	Lithium-ion – 3x3.6V, 3200 mAh.	Ni-MH AA – 1.2V x4 (4.8V), 2000 mAh
Weight	Approximately 4 lbs.	Approximately 26 ozs.
Size	8.5” x 9.75” x 5”	2.25” x 4.875” x 6.5”
Sterility	Non-sterile	Non-sterile
Operating Temperatures	Operating: 59 to 104 degrees F (15 to 40 degrees C) at relative humidity of 30%-	Operating: 59 to 104 degrees F (15 to 40 degrees C) at relative humidity of 30%-90% (non-

Attribute	New Device ViaTherm ViVy System	Proposed Predicate ViaTherm BOOST K173300
	90% (non-condensing) and pressure of 700-1060 hPa.	condensing) and pressure of 700-1060 hPa.
Storage Temperatures	Storage: 50 to 140 degrees F (10 to 60 degrees C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.	Storage: 50 to 140 degrees F (10 to 60 degrees C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.
Radiation Safety	Established	Established
RF Shielding	Yes	Yes
Designed to meet Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60606-1-6 IEC 60601-1-11 IEC TR 60601-4-2 ANSI AAMI HA60601-1-11 AIM 7351731	IEC 60601-1 IEC 60601-1-2 IEC 60606-1-6 IEC 60601-1-11
Coil design	Two flat spiral coils embedded in a fabric garment	Two flat spiral coils embedded in a fabric garment

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ViaTherm ViVY™ Summary, Continued

Discussion

The ViVy System and the predicate device (BOOST System) is intended to deliver deep heating to tissues for the purpose of generating deep heating, relieving pain, and treatment of muscle spasms.

All devices are designed to be used by non-technical individuals.

Induction coil diathermy is utilized by both the subject and predicate device. The shortwave diathermy devices use a radiofrequency (RF) signal that is generated by electronic circuitry at 13.56 MHZ to induce electrical currents and voltages in body tissues. The radiofrequency is delivered to an applicator that produces electromagnetic fields external to the applicator. Electric and magnetic fields are induced in body tissues by the applicator. The induced flow of RF electric current in tissue induces heating.

Vivy operates at 10W. This power level is higher than BOOST, but bench temperature testing demonstrates that body tissues remain within a safe therapeutic range.

The subject and predicate devices are based on the following same technological elements:

- Radiofrequency (RF) signal generator that produces a continuous power
- Control circuitry that manipulates the operating parameters of the system
- Patient applicator (garment)
- Portable design
- Rechargeable battery

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ViaTherm ViVY™ Summary, Continued

Performance testing

The following tests were performed to verify the safety and effectiveness of the Vivy device.

- ASCA Safety Testing
- IEC 60601-1-2:2014+A1:2020
- IEC TR 60601-4-2:2016
- IEC 60601-1 Edition 3.2 2020-08 Consolidated Version
- ANSI AAMI HA60601-1-11:2015 (including AMD1:2021)
- ASCA EMC testing
- Output Power Adjustment Testing
- Electrical Safety, EMC, and Environmental Testing
- Shipping tests
- Usability
- Primary Label and Device Markings
- Instructions for Use Warnings
- Instructions for Use Tasks

Clinical testing

Twelve volunteer subjects (4 male; 8 female) were recruited and participated in a study to investigate tissue temperature changes during continuous shortwave diathermy within the thigh muscle.
Characteristics of the subjects:

- Average age was 23$\pm$3.4 years.
- Height was 164.9$\pm$7.2cm.
- Weight 71$\pm$13.2kg.

The maximum temperature rise achieved:

- Skin surface was 8.46$\pm$2.2°C at 20 minutes
- 1cm depth (superficial tissue) was 3.34$\pm$1.5°C at 35 minutes
- 2 cm depth (deep tissue) was 1.61$\pm$0.81°C at 40 minutes

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ViaTherm ViVY™ 510(k) Summary, Continued

Conclusion

The preclinical and clinical performance of the Vivy System demonstrates that it is substantially equivalent to the predicate device. The ViVy System has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. Both ViVy and BOOST are indicated for over-the-counter use. The minor difference in the battery (rechargeable for Vivy) as compared to the predicate raises no new issues of safety or effectiveness.

Based on the technical characteristics and the results of the performance testing, the ViVy System is substantially equivalent to the predicate.