November 23, 2022

NanoVibronix, Inc.
Hrishikesh Gadagkar
Regulatory Affairs
525 Executive Blvd.
Elmsford, New York 10523

Re: K221210
Trade/Device Name: PainShield MD PLUS
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: April 23, 2022
Received: April 27, 2022

Dear Hrishikesh Gadagkar:

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,

Lauren E. Woodard -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221210

Device Name
PainShield MD PLUS

Indications for Use *(Describe)*
The PainShield MD PLUS is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Date of the summary prepared: November 22, 2022

Submitter's Information:

510(k) Owner's Name: NanoVibronix, Inc.

Address: 525 Executive Blvd., Elmsford, NY 10523

Phone: (410) 245-0501

Contact Name: Hrishikesh Gadagkar

Contact Email: gadagkar@idonea-solutions.com

Device Information:

Manufacturer: NanoVibronix, Inc.

Trade Name: PainShield MD PLUS

510(k) Number: K221210

Product Code: PFW

Device Classification: Class II

Regulation Number: 21 CFR 890.5300

Predicate Device:

Manufacturer: NanoVibronix, Inc.

Trade Name: PainShield MD

510(k) Number: K081075

Product Code: PFW

Device Classification: Class II

Regulation Number: 21 CFR 890.5300

Device Description:

The PainShield MD PLUS is an electrically powered ultrasonic diathermy device intended to relieve pain, muscle spasms, and joint contractures. It is used to apply deep heat to tissues in the body with a transducer/applicator that is incorporated into a bandage-like patch that adheres to the skin.

The PainShield MD PLUS is used to generate continuous wave (CW) ultrasound at 90 kHz, through a reusable applicator/transducer that covers an area of about 6 cm^2. The small applicators allow treatment of less accessible body parts such as, for example, the heel, the Achilles tendon and the wrist. The device includes the above-mentioned transducers with a cable which connects to a small, rechargeable, battery-powered driver unit and self-adhering patch to apply the transducer on to the skin. The unit is also supplied with a charger used for recharging the battery. Ultrasonic gel is typically not required to be used with the PainShield MD PLUS device. However, for treatment over hairy sites where there might not be adequate sonic coupling between the applicator and the skin, users are instructed to apply standard, FDA-cleared ultrasound gel to the site to improve coupling.

Indications for Use:

The PainShield MD PLUS is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.

Test Summary for PainShield MD PLUS:

Test	**Summary Results**
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + A1:2012 (3rd Edition), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	All applicable tests passed.
IEC 60601-1-2: 2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard, Electromagnetic Compatibility	All applicable tests passed.
IEC 60601-1-11: 2015 (2nd Edition) General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical	All applicable tests passed.

equipment and medical electrical systems used in the home healthcare environment.	
Biocompatibility Testing ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	All applicable tests passed.
Software Verification and Validation	All applicable tests passed.

Comparison to Predicate Device:
The technological characteristics, features, specifications, materials, mode of operation, and intended use of PainShield MD PLUS System is substantially equivalent to the predicate device (PainShield MD).

The differences between the PainShield MD PLUS and the predicate device do not raise new issues of safety or effectiveness.

Parameter	PainShield MD PLUS	PainShield MD
510(k) Number	K221210	K081075
Indications for Use	The PainShield MD PLUS is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.	The PainShield MD diathermy device is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.
Classification	Class II 21 CFR 890.5300 Ultrasonic Diathermy	Class II 21 CFR 890.5300 Ultrasonic Diathermy
Product Code	PFW	PFW
Principle of Operation	Device applies deep heat to tissues	Device applies deep heat to tissues

Major System Components	(Ultrasound) Driver	(Ultrasound) Driver
	Separate (Ultrasound) Actuator and Self-adhesive Patch	Actuator and Self-adhesive Patch
	AC Adapter	Not Publicly Available
Performance Specifications		
Energy source frequency	90 kHz	90 kHz
Output power:	400 mW	Not Publicly Available
Output modes	CW	Not Publicly Available
Output channels	2	Not Publicly Available
Transducer	Two 6 cm^2 disk shaped transducers	One 6 cm^2 disk shaped transducer
Transducer material	Lead Zirconate-Titanate PZT	Not Publicly Available
Maximum Beam Non-Uniformity Ratio	6.0:1	Not Publicly Available
Effective Radiating Area	6 cm^2	6 cm^2
Therapy Cycle	For each actuator, alternate between 30 minutes Active Phase followed by 30 minutes of Idle Phase for a total duration of 3 hours. Treatment can be shut off anytime manually.	Not Publicly Available
Physical Size and Controls		
Physical Dimensions	Height: 113 mm	Not Publicly Available
	Width: 39.4 mm	Not Publicly Available
	Depth: 12.6 mm	Not Publicly Available
Weight	~227 grams	Not Publicly Available
Display:	LED and buzzer status indicators and digital LCD timer display.	Not Publicly Available

Battery type recommended:	Rechargeable lithium ion battery	Rechargeable battery
Battery Voltage:	7.4 V	Not Publicly Available
Battery Life:	3 hours continuous operation	Not Publicly Available
Mode of operation	Continuous wave	Not Publicly Available

The technological characteristics, features, specifications, materials, mode of operation, and intended use of PainShield MD PLUS is substantially equivalent to the predicate device (PainShield MD). The differences between the PainShield MD PLUS and the predicate device (such as two actuators, separation of the actuator, and self-adhesive patch) do not raise new issues of safety or effectiveness. The second actuator available with PainShield MD PLUS is intended to increase the physical area over which the therapy is made available. The tandem operation of the two actuators does not introduce new safety concerns for the user. The separation of the actuator and the self-adhesive patch improves the ability to reuse the actuator and replace the self-adhesive patch after each use.

Conclusion:

The PainShield MD PLUS is substantially equivalent to the predicate device (PainShield MD manufactured by NanoVibronix, Inc.).