December 23, 2025

DynaPulse Medical
% Danielle Besal
Principal Consultant
MRC Global
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K251958
Trade/Device Name: VEINOPLUS Back
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: November 19, 2025
Received: November 20, 2025

Dear Danielle Besal:

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,

JITENDRA V. VIRANI -S

CDR Jitendra Virani, MS MBA
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.

510(k) Number *(if known)*
K251958

Device Name
VEINOPLUS Back

Indications for Use *(Describe)*
The Veinoplus® Back is to be used for temporary relief of pain associated with sore and aching muscles in the back (shoulder, middle of the back, or lumbar area), due to strain from exercise or normal household and work activities.

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."

510(k) Summary
K251958
VEINOPLUS Back
December 16, 2025

Company: DynaPulse Medical
13500 Wayzata Blvd
Minnetonka, MN 55305

Primary Contact: Danielle Besal
Principal Consultant | MRC Global
901.827.8670
Danielle.Besal@askmrcglobal.com

Company Contact: Steffen Magnell
CEO | DynaPulse Medical
612.464.3872
Steffen.Magnell@dynapulsemedical.com

Trade Name: VEINOPLUS Back
Common Name: Transcutaneous electrical nerve stimulator for pain relief
Classification Name: Stimulator, nerve, transcutaneous, over-the-counter
Classification: Class II
Regulation Number: 21 CFR 882.5890
Product Code: NUH
Predicate Device: K130802: OTC Electrical Stimulator Models MT900I, LT3060

Device Description:
VEINOPLUS Back is a non-invasive, battery-operated, over-the-counter device that provides transcutaneous electrical nerve stimulation (TENS). The VEINOPLUS Back consists of the handheld device with LCD screen and button controls, self-adhesive electrodes, cable to connect the device to the electrodes, 9V battery, and optional carrying accessories. When the device is in use, the on/off status, battery indicator, and stimulation intensity are displayed on the device's screen. The user is able to control the stimulation intensity via the button controls on the device and the device includes safety features such as automatic shut-off and patient override control.

Indications for Use:
The Veinoplus® Back is to be used for temporary relief of pain associated with sore and aching muscles in the back (shoulder, middle of the back, or lumbar area), due to strain from exercise or normal household and work activities.

Indications for Use Comparison:
Both the subject and predicate devices are indicated for TENS (temporary relief of pain from sore and aching muscles). Although the subject device is designed for use on the

back, this target area is a subset of that indicated for the predicate and, therefore, the indications for use are considered substantially equivalent to those of the predicate.

Technological Comparison:
The technological characteristics of the subject device are comparable to those of the predicate device. The subject device operates using the same mechanism of action as the predicate device. It also has a similar form factor of a handheld unit connected to self-adhesive electrodes, battery power source, user controls, and safety features. There are some differences between the output specifications of the subject device in comparison to the predicate; however, the specifications are within the range of those of the predicate and any differences were deemed negligible. Table 1 provides a complete comparison of the technological characteristics of the subject and predicate devices.

Performance Testing:
Electrical safety and performance testing was completed on the device in accordance with the following standards: IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10. Results of the testing demonstrated equivalence with the predicate devices.

Conclusion:
The subject device has the same intended use as the predicate device and operates through the same mechanism of action. Although there are some differences in the technical output specifications, the subject device specifications are within the range of those of the predicate and there were no different questions of safety or effectiveness raised by the differences. Testing on the device demonstrated compliance with applicable safety and performance standards and, thus, with the predicate device. In conclusion, VEINOPLUS Back is considered substantially equivalent to the identified predicate device.

Table 1. Comparison of Subject and Predicate Devices

	SUBJECT	PREDICATE
	VEINOPLUS Back	**OTC Electrical Stimulator Models MT900I, LT3060 K130802**
Product code	NUH	NUH, NGX
Indications for Use	The Veinoplus® Back is to be used for temporary relief of pain associated with sore and aching muscles in the back (shoulder, middle of the back, or lumbar area), due to strain from exercise or normal household and work activities.	MT9001-TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. LT3060 -TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
Rx or OTC	OTC	OTC
Functions	Electrical stimulation	Electrical stimulation
Power source	9V alkaline battery	9V battery
Method of line current isolation	Complete; no connection (uses battery power only)	N/A
Patient leakage current	N/A (normal and single fault conditions)	0.61μA (normal), 0.68uA (single fault condition)
Average DC current through electrodes when device is on, but no pulses being applied	0	0
Number of output modes	1	1 TENS, 1 EMS
Number of output channels	1	Alternating
Synchronous / Alternating	N/A	
Method of channel isolation	N/A	By electrical circuit and software
Regulated current or voltage	Voltage	Current
Software / Firmware / Microprocessor Control	Yes	Yes
Automatic Overload Trip	No	Yes
Automatic No-Load Trip	No	Yes
Automatic Shut Off	Yes	Yes
Patient Override Control	Yes	Yes
User Display	On/off status, battery indicator, stimulation intensity (equal to	On/off status, low battery, voltage/current level

		SUBJECT **VEINOPLUS Back**	PREDICATE **OTC Electrical Stimulator Models MT900I, LT3060 K130802**
		peak value of output voltage on 500Ω load with 5% accuracy)	
Battery cut-off voltage		5.6 V ±10%	Unknown
Timer		45 min	1-60 min
Weight		160g	128g
Dimensions (WxHxD)		150x60x21mm	117x60x34mm
Housing materials		ABS & PC	ABS
Electrical safety		IEC 60601-1 compliant	IEC 60601-1 compliant
EMC		IEC 60601-1-2 compliant	IEC 60601-1-2 compliant
Performance		IEC 60601-2-10 compliant	IEC 60601-2-10 compliant
Waveform		Monophasic, rectangular asymmetric	Biphasic, square
Maximum Output Voltage (V)		50±5% @ 500 Ω 50±5% @ 2 kΩ 50±5% @ 10 kΩ	96±20% @ 500 Ω 200±20%; 228±20% @ 2 kΩ 210±20%; 230±20% @ 10 kΩ
Maximum Output Current (mA)		100±0% @ 500 Ω 25±10% @ 2 kΩ 5±10% @ 10 kΩ	96±20% @ 500 Ω 50±20%; 57±20% @ 2 kΩ 10.5±20%; 11.5±20% @ 10 kΩ
Pulse width (µs)		25-240	50-300
Frequency (Hz)		1-120	1-150
Net charge DC / microcoulombs (µC) per pulse		< 0.6	0
Maximum phase charge (µC)		24 @500 Ω	28.8 @500 Ω
Maximum current density (mA/cm^2)		1 @500 Ω	1.15 @500 Ω
Maximum power density (using smallest electrode conductive surface area) (mW/cm^2)		50 @500 Ω	0.373 @500 Ω
Burst mode (pulse trains)	**Pulses/burst**	60	7
	Bursts/sec	1.25	0.5/1/2/3/4/5 Hz
	Burst duration	0.1 seconds	70 ms
	Duty cycle (bursts/sec x burst duration)	0.125	0.1
On time (s)		0.1	N/A; 1-30
Off time (s)		0.9	N/A; 1-60

	SUBJECT	PREDICATE
	VEINOPLUS Back	**OTC Electrical Stimulator Models MT900I, LT3060 K130802**
Additional feature	Each train of pulses is preceded by a ramp (pulse width modulation from 65µs-135µs)	Unknown