February 8, 2024

Artaflex Inc.
Gerry Iuliano
Owner
181 Whitehall Drive
Markham, Ontario L3T 9T1
Canada

Re: K231575
Trade/Device Name: Vecttor VT-300
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: LIH
Dated: February 8, 2024
Received: February 8, 2024

Dear Gerry Iuliano:

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.

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,

Robert Kang -S

for Pamela Scott, MS
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)*
K231575

Device Name
Vecttor VT-300

Indications for Use *(Describe)*
Electrical stimulation delivered by the device is intended for the symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain.

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.

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510(k) SUMMARY

VECTTOR VT-300

Submitter's name, address, telephone number, a contact person:

Gerry Iuliano, Owner

Artaflex Inc. – 181 Whitehall Dr., Markham Ontario L3T 9T1 Canada.

TEL: 905.470.0109 | FAX: 905.470.0621

Date the summary was prepared;

February 6, 2024

Name of the device

Trade Name: VECTTOR VT-300

Common Name: Interferential Current Therapy Device

Classification Name: Interferential Current Therapy

Product Code: LIH

Identification of the legally marketed device to which the submitter claims equivalence.

K121662 VECTTOR VT-200

Description of the device

VT-300 device is portable and battery operated. VT-300 Device is comprised of a PCBA and a lithium-ion battery enclosed in a polycarbonate housing. The device's dimensions are 2.1 inches wide, 3.3 inches long, and 0.75 inch in height.

Vecttor VT-300 provides Interferential Current Therapy. Eight electrodes attached to a pair of lead wires are intended to be positioned on the patient's body to deliver four channels of current from VT-300 dual output jacks. Temperature sensors continually monitor finger surface temperatures with the intention of identifying and then applying an Interferential Current Therapy level that results in specified temperature increases.

The user controls the VT-300 device using Vecttor Mobile App which is a mobile application downloadable on Bluetooth enabled mobile devices using Android or iOS operating systems from the Google Play or Apple App store. Vecttor Mobile App provides the necessary user interface to establish connection to the VT-300 device via Bluetooth, and operate VT-300 device to provide interferential current therapy.

A statement of the intended use of the device

Electrical stimulation delivered by the device is intended for the symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain.

Comparison of the technological characteristics with predicate device

Vecttor VT-300 represents a modified version of predicate device Vecttor VT-200 (K121662) implementing design changes requested by applicant of K121662 for VT-200 predicate device, Dr. Donald Rhodes:

- Modernized redesign including reduced size, wiring, and relocation of connection ports
- Change power supply to on-board battery
- Change thermistor temperature sensor to digital temperature sensor
- Change SD card with cloud-based application for managing patient treatments and data
- Change device display screen and tactile buttons interface to mobile device screen and software application

VT-300 has the same intended use and similar technological characteristics and principles of operation as K121662 for VT-200 predicate device. Any differences in technological characteristics potentially raising questions of safety or effectiveness have been addressed through Bench Performance Testing and compliance with FDA recognized consensus standards.

OUTPUT SPECIFICATIONS			
#	**Characteristics**	**Subject Device**	**Predicate Device (K121662)**
0	510(k) Number	K231575	K121662
1	Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic
2	Shape (e.g., rectangular, spike, rectified sinusoidal)	Pure Sinusoid	Pure Sinusoid
3	Maximum Output Voltage (volts p/p)	4.36 @ 500 Ω 6.72 @ 2 kΩ 8.08 @10 kΩ	4.36 @ 500 Ω 6.72 @ 2 kΩ 8.08 @10 kΩ
4	Maximum Output Current (mA RMS)	3.08 @ 500 Ω 1.19 @ 2 kΩ 0.29 @10 kΩ	3.08 @ 500 Ω 1.19 @ 2 kΩ 0.29 @10 kΩ
5	Pulse Width (µsec)	Continuous Sine Wave	Continuous Sine Wave
6	Frequency (Hz) [or Rate (pps)]	1500Hz – 1580Hz 2500Hz – 2580Hz	1500Hz – 1580Hz 2500Hz – 2580Hz
7	For interferential modes only: - Beat Frequency (Hz)	1000Hz	1000Hz
8	For multiphasic waveforms only: - Symmetrical phases?	Yes	Yes
9	- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	N/A	N/A
10	Net Charge (mC per pulse)	0 @ 500 Ω Outputs have no DC output by means of DC blocking capacitor and isolation transformers at outputs	0 @ 500 Ω Outputs have no DC output by means of DC blocking capacitor and isolation transformers at outputs
11	Maximum Phase Charge, (µC) @500 Ω	0.93 uC	0.93 uC
12	Maximum Current Density, (mA/cm², r.m.s.) @500 Ω	0.39	0.39
13	Maximum Power Density, (W/cm²) using smallest electrode conductive surface area @500 Ω	0.6	0.6
14	Burst Mode	N/A	N/A
15	ON Time (seconds)	5	5
16	OFF Time (seconds)	1	1

17	Average DC current through electrodes when device is on but no pulses are applied	Zero	Zero
	Mode or Program Name	1	1
	Duration of primary (depolarizing) phase (msec)	N/A	N/A
	Maximum Average Current (average absolute value), mA @500 Ω	0 (No DC contents present)	0 (No DC contents present)

A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

VT-300 system and software verification & validation has been conducted to ensure design output meets the design input requirements. In addition, VT-300 complies with the following FDA recognized consensus standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

No clinical tests are being submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Conclusions

VT-300 has the same intended use as its predicate device. Any differences in technological characteristics potentially raising questions of safety or effectiveness have been addressed through Bench Performance Testing and compliance with FDA recognized consensus standards. In conclusion, VT-300 is substantially equivalent to VT-200.