DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 12, 2017

Avazzia, Inc.
Tammy Lahutsky
Regulatory Affairs
13140 Coit Road
Suite 515
Dallas, Texas 75240
(214) 575-2820 [voice]
(214) 575-2824 [fax]
tlahutsky@avazzia.com

Re: K162392
Trade/Device Name: Avazzia OTC TENS Model Best-AV1™: Med-Best™, Med-Sport™, Avazzia Blue™, Avazzia Star™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: April 12, 2017
Received: April 14, 2017

Dear Tammy Lahutsky:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.05.12 09:54:28 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162392

Device Name
Avazzia OTC TENS Model Best-AV1™: Med-Best™, Med-Sport™, Avazzia Blue™, Avazzia Star™

Indications for Use *(Describe)*
Transcutaneous Electrical Nerve Stimulation (TENS) for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household 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.

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510(k) Summary

Submitter's Identifications:

Manufacturer and Sponsor:
Avazzia, Inc.
13140 Coit Road., Suite 515
Dallas, TX 75240 USA
Tel. 214-575-2820
Establishment Registration # 3004839404
Official Contact Person: Tammy Lahutsky
Date of Summary Preparation: August 18, 2016

Trade Names of Candidate Devices:

Avazzia OTC TENS Model Best-AV1™: Med-Best™, Med-Sport™, Avazzia Blue™, Avazzia Star™

Classifications: TENS, Class II 21 CFR 882.5890 NUH

Information of the 510(k) Cleared Devices (Predicate Devices):

Primary Predicate:

Prospera OTC TENS Electronic Pulse Massager, Models PL009, PL009A, and PL029, K122744 03/28/2013, TENS Class II 21 CFR 882.5890 NUH, NGX

Reference Devices:

Avazzia TENS Model BEST-AV1™, K062641, 4/30/2007, TENS, Class II 21 CFR 882.5890 GZJ
Avazzia TENS Model Best-AV2™, K123099, 05/23/2014, TENS, Class II, 21 CFR 882.5890, GZJ
Gemore Technology Co. LTd. Low back pain relief system, models model GM310PP, GM320PP, GM321PP, K060222, 04/28/2006, TENS Class II 21 CFR 882.5890 NUH

Intended Use:

Transcutaneous Electrical Nerve Stimulation (TENS) for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Description of Candidate Devices:

Description of Candidate Devices as might be found in the labeling or promotional material:
Avazzia OTC TENS electronic pulse massage devices are electrically powered device intended for over-the-counter use and used to apply a microcurrent electrical pulses to electrodes on a user's skin to relieve pain. They are easy-to-use, handheld, AA battery-operated portable devices for use in the home or clinic. The candidate devices have pre-set modes.

Description of the Candidate Devices – How the devices work:
The devices are portable, battery operated microcurrent electrical stimulation device that applies charge and power to the tissue through electrodes where maximum power delivered to the load is controlled and limited, and an automatic shut off is implemented.

The user can apply the built-in onboard electrodes or place self-adhesive conductive electrodes where indicated and apply stimulation for a period of time.

The user controls the output by selecting the mode and power setting.

Scientific Concepts that form the basis of the devices:

Various modes in the candidate device are suited for TENS applications.

Design Description: Significant physical and performance characteristics of the device including stimulation output specifications & Summary of the Technological Characteristics Compared to the Predicates are shown below:

Discussion of any different technological characteristics between the devices and the predicate devices:

The candidate devices have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device as summarized in the table of the technological characteristics.

Accessories

Self-adhesive conductive electrode pads
Soft tissue electrodes with common name: Y electrodes
Lead wires

Nonclinical tests

Verification and validation tests as well as certificates and test reports contained in this submission demonstrate that the submitted models are substantially equivalent to the safety and effectiveness as that of the cleared devices.

The software verification is conducted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff – May 11, 2005.

The candidates devices and accessories meet general safety requirements IEC 60601-1 and requirements EMC: IEC 60601-1-2.

Safety and effectiveness

The Avazzia device technological specifications are the same; therefore, they do not pose new questions regarding safety and effectiveness.

Indications for use for TENS OTC has been established, therefore, indications for use do not pose new questions regarding safety and effectiveness.

Basis for a determination of substantial equivalence:

- *Do the candidate Devices have the same indications for use?* Yes
- *Do the candidate Devices have the same Technological Characteristics?* Yes

- *Do the candidate devices pose any new questions regarding safety of effectiveness?* No
- *Do the candidate devices have accepted scientific methods for evaluating safety and effectiveness?* Yes
- *Do the candidate devices demonstrate no diminishment of performance?* Yes

Conclusions:
The Avazzia OTC TENS Model BEST – AV1™ devices have intended uses and technological characteristics that are substantially equivalent to predicate devices.

Summary of Technical Characteristics			
		Candidates	**Predicate**
Device Name and Model		BEST-AV1, Med-Best, Med-Sport, Avazzia Blue, Avazzia Star	Models PL009, PL009A, and PL029
Manufacturer		Avazzia, Inc.	Propera
Power Source		Two 1.5 V AA batteries	Four 1.5 V AAA batteries
Method of Line Current Isolation		Battery Supply N/A	Battery Supply N/A
Patient Leakage Current - Normal Condition - Single Fault Condition	 µa µa	 13.7 27	 1.8 3.3
Average DC current through electrodes when device is on but no pulses are being applied	µa	0	0
Number of output modes	Number	2, 4	3
Number of output channels: - Synchronous/Alternating? - Method of Channel Isolation		1 n/a n/a	Synchronous ON/Off Switch or By Software
Regulated Current or Regulated Voltage		Voltage control	Voltage control
Software control		Yes	Yes
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		Yes	No
Automatic Shut Off?		Yes	Yes
User Override Control?		Yes	Yes
Indicator Display - On/Off Status? - Low Battery? - Voltage/Current intensity?		 Yes Yes Yes	 Yes No No
Timer Range	Minutes	60	5, 10, or 15
Compliance with Voluntary Standards?		Yes	Yes
Compliance with 21 CFR 898		Yes	Yes
Weight	oz	7	8
Dimensions	In	4.6 x 2.5 x 1.3 (117mm X 64mm X 33mm)	2.2 x 7.8 x 0.9
Housing materials and construction		Enclosure: ABS	Enclosure: ABS
Wavform		Biphasic	monophasic
Shape		positive square wave followed by a damped sinusodial waveform of variable duration depending on damping and body loading	regular

Summary of Technical Characteristics			
		Candidates	**Predicate**
Device Name and Model		BEST-AV1, Med-Best, Med-Sport, Avazzia Blue, Avazzia Star	Models PL009, PL009A, and PL029
Max output voltage (+/- 20%) - at 500 Ω - at 2,000 Ω - at 10,000 Ω	 V V V	 -42 -122 -348	 12.8 51 368
- Max output current (+/- 20%) - at 500 Ω - at 2,000 Ω - at 10,000 Ω	 uA uA uA	 3080 451 535	 15,000 3,200 600
Duration of primary (depolarizing phase)	µSec	506	0.040
Pulse Duration	uSec	1100	120 to 6800
Frequency	Hz	20 to 185	1 to 100
Net Charge per pulse at 500 Ω	uC	4.0	18,000
Max Charge per pulse at 500 Ω	uC	10.12	23
Max current density at 500 Ω	mA/cm2	1.6	1.4
Max average power density at 500 Ω	mW/cm2	2.445	230
Burst mode (a) pulse per burst (b) burst per second (c) burst duration (sec) (d) Duty Cycle		 Up to 8 Up to 77 Up to 6mSec 46%	 1 0-25 1 5
On Time	Sec	0.46	Potentiometer switch
Off time	Sec	0.54	Potentiometer switch
Additional Features		N/A	N/A