April 27, 2021

Avazzia, Inc
Ms. Tammy Lahutsky
Regulatory Affairs
13140 Coit Road, Suite 515
Dallas, Texas 75240

Re: K191951
Trade/Device Name: Avazzia OTC TENS for Aesthetics, model BEST-AV1: EZZI-LIFT Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: March 25, 2021
Received: March 26, 2021

Dear Ms. 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. 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,

Jitendra Virani
Acting 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)*
K191951

Device Name
Avazzia OTC TENS for Aesthetics, model BEST-AV1™: EZZI-LIFT™ Device

Indications for Use *(Describe)*
The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.

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.

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510(k) Summary

Submitted by:

Manufacturer and Sponsor:	Avazzia, Inc. 13140 Coit Road Suite 515 Dallas, TX 75240 USA
Telephone:	214-575-2820
Contact Person:	Tammy Lahutsky

Date of Summary Preparation:	April 26, 2021
Trade Names of Candidate Devices:	Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device

Device names:

Device Trade Proprietary name:	Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device
Device Common or Usual Name:	Aesthetic TENS Device
Classification Name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulation Number:	21 CFR 882.5890
Regulation Class	Class II
Product code:	NFO

Predicate Devices

- NuFACE Trinity Facial and Neck Skin Toning Device, K181008, 08/14/2018, TENS Class II 21 CFR 882.5890 NFO (primary predicate)
- NuBODY Skin Toning Device, K171588, 07/27/2017, TENS Class II 21 CFR 882.5890 NFO (secondary predicate)

Reference Device used to support scientific methodology

- Avazzia OTC TENS Model Best-AV1™: Med-Best™, Med-Sport™, Avazzia Blue™, Avazzia Star™, K162392, 05/12/2017, TENS Class II 21 CFR 882.5890 NUH is identical in manufacturing to the candidate device and is used to support biocompatibility, electromagnetic compatibility and electrical safety testing.

Indications for Use

The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.

Description of Candidate Device

Candidate device is a handheld, AA battery-operated portable device for use in the home or clinic. It has pre-set modes and is for over-the-counter use in the home or a clinical setting.

The candidate device uses transcutaneous electrical stimulation (TENS) for aesthetic use for facial, neck, and body stimulation.

How the Device Works

Candidate device uses TENS applied to the skin surface with cutaneous electrodes to stimulate the skin of the face, neck and body for aesthetic use.

The EZZI-LIFT device has built-in electrodes. Accessories, listed below, are also available to be used with the device.

Available Accessories

- Cutaneous electrodes:
  - Spherical Soft tissue electrodes with common name: Y electrodes
  - Brush electrode
  - Small Circular Electrode with common name: Pencil electrode
- Lead wires

The user can apply the built-in electrodes or place accessory electrodes where indicated and apply stimulation for a recommended period of time. The user manual contains recommended treatment methods and times.

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

Scientific Concepts

Various modes in the candidate device are suited for TENS applications. Very short duration high voltage pulsed current (HVPC) stimulates the skin of the face, neck and body for aesthetic use.

Predicate Comparison

Significant physical and performance characteristics of the device including Stimulation Output Specifications & Summary of the Technological Characteristics Compared to the Predicates are shown in the table below.

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

Device Comparison Table (i.e., design, material, chemical composition, energy source)				
Characteristic	**units**	**Candidate**	**Primary Predicate**	**Secondary Predicate**
Device Name		**EZZI-LIFT**	**NuFACE Trinity**	**NuBody**
510K		K191951	K181008	K171588
Manufacturer		Avazzia, Inc.	Carol Cole Company (dba NuFACE)	Carol Cole Company (dba NuFACE)
Indications for Use		The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	The NuFACE Trinity Device is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.	NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.
Anatomic Sites		Face, neck, and body	Face and neck	Body
Number of Output Modes	number	4	1	1
Low Battery Indicator		Yes	Yes	Yes
Automatic shut off	(minutes)	60	20	5
Compliance with Voluntary Standards	Yes/No	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60529, ISO 14971 IEC 60601-1-6 IEC 62366
Compliance with 21 CFR 898	Yes / No	Yes	Yes	Yes
Weight	ounces	5.4	9	10 to 14
Dimensions [W x H x D]	(in.)	2.6” X 4.7” X 1.35”	2.8" x 5.1" x 1.3"	2" x 6.5" x 6.0"
Housing Materials and Construction		PCBs inside plastic case housing	Thermoplastic	Thermoplastic
User Interface Display		LEDs and switches	not publicly available	not publicly available
Energy type		Electric stimulation	Electric stimulation	Electric stimulation
Number, Size, and Type of Batteries		Two 1.5 V AA batteries	Internal rechargeable Lithium-ion battery	Internal rechargeable Lithium-ion battery

Stimulation Output Specifications				
Characteristic	**units**	**Candidate**	**Predicate**	**Predicate**
Device Name		**EZZI-LIFT**	**NuFACE Trinity**	**NuBody**
Waveform Shape		positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading	pulsed biphasic modulated square wave	monophasic voltage modulated square wave
Max output voltage (+/- 20%)				
- at 500 Ω	V	-42	28	28
- at 2,000 Ω	V	-122	not publicly available	not publicly available
- at 10,000 Ω	V	-348	not publicly available	not publicly available
Max output current (+/- 20%)		500µA		
- at 500 Ω	µA	363	400	900
- at 2,000 Ω	µA	117	not publicly available	not publicly available
- at 10,000 Ω	µA	38	not publicly available	not publicly available
Duration of primary (depolarizing phase)	mSec	0.5	60	60
Pulse Duration	mSec	1.1	60	60
Frequency	Hz	15 to 121	8.3	8.3
Net Charge per pulse at 500 Ω	µC	4	not publicly available	54
Max phase charge	µC	10	not publicly available	not publicly available
Max current density at 500 Ω	µA/cm²	Built-in, Y, Brush: 800 Pencil: 19,000	419	468
Max average power density at 500 Ω	µW/cm²	Built-in, Y, Brush: 500 Pencil: 3,500	not publicly available	4,180
Burst mode				
(a) pulse per burst	number	1	20	20
(b) burst per second	number	n/a	8.3	8.3
(c) burst duration	(sec)	n/a	2.4	2.4
(d) duty cycle		n/a	20.2sec	20.2sec
On Time (per second)	seconds	0.1	not publicly available	not publicly available
Off Time (per second)	seconds	0.9	not publicly available	not publicly available
Electrodes				

Stimulation Output Specifications				
Characteristic	**units**	**Candidate**	**Predicate**	**Predicate**
Device Name		**EZZI-LIFT**	**NuFACE Trinity**	**NuBody**
(a) materials		Stainless steel 316	Chrome-plated	Chrome-plated
(b) electroconductive media		n/a	Conductive gel	Conductive gel
(c) electrode-to-skin impedance range		less than 15	not publicly available	not publicly available
(d) max duration of use (same as device shut off)	(minutes)	60	20	20
(e) conductive surface area				
built in rectangular	cm2	1.94	-	-
spherical	cm2	5.60	not publicly available	not publicly available
brush/comb	cm2	0.56	not publicly available	not publicly available
small circular, pencil-like	cm2	0.023	not publicly available	not publicly available

Comparison of technical characteristics with the predicate devices

Transcutaneous electric nerve stimulation (TENS) is the technological principle for both the subject and predicate devices. It is based on the use of electric stimulation to the skin for aesthetic use.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Transcutaneous electric nerve stimulation (TENS) to the skin for aesthetic use
- Quantity of electric stimulation applied to the skin resulting from short, pulsed electrical current that results in only microamperage applications per second, also known as microcurrent.
- Meet the same medical device general safety requirements IEC 60601-1 and requirements EMC: IEC 60601-1-2.

There are variations between the subject and predicate devices for specific waveform shape, max voltage, phase charge, pulses per second, duty cycle and current.

Rationale that differences in technical performance specifications are within range of equivalence, and therefore, do not raise new questions.

The variations in technical characteristics fall within the range of Agency accepted differences for devices with the same principal of operation and the same intended use. This is consistent with the Agency accepted standard, ANSI/AAMI NS4:2013/ (R)2017 Transcutaneous electrical nerve stimulators, that references combination of current or charge over time for determining safety for Transcutaneous electrical stimulators.

The ANSI/AAMI document established a maximum charge to prevent serious injury or death.

Peak instantaneous maximum voltage and pulse width are considered and included in determination of charge per pulse and the resulting current flow and determining safety.

The candidate devices fall within the same range of equivalence for performance and energy output for meeting the ANSI/AAMI NS4:2013/(R)2017 standard requirements for safety; and therefore, they do not raise new questions of safety.

Nonclinical Tests

Nonclinical bench testing was performed to demonstrate that the candidate device met design specifications and accepted safety standards and requirements.

Performance testing was conducted using a production equivalent of the candidate device. The testing consisted of the evaluation of output waveform and energy characteristics. Results were compared to predicate device performance characteristics.

Additionally, output energy, electrical and constructional safety and EMC testing of the candidate device was conducted in accordance with Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, IEC 60601-1:2005 MOD, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, IEC 60601-1-2, Edition 4.0 2014-02, and Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators, IEC 60601-2-10, 2016.

The software development process and software verification is conducted according to Medical device software – Software life cycle processes, IEC 62304, 2015 and the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff – May 11, 2005.

Usability study was performed to assess the candidate device for aesthetic use. The candidate device and accompanying instructions for use met requirements for usability factors for over-the-counter use. No new questions of safety or efficacy were raised. No new risks were raised. The instructions for use support the safe and effective use of the EZZI-LIFT device and accessories for aesthetic use. Reference FDA guidance, “Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff”, 2016 and IEC 62366, Medical devices – Part 1: Application of usability engineering to medical devices, 2015.

Results from bench testing and performance tests are compared to that of predicate devices in a comparison table format.

Nonclinical test results and studies, including the performance bench testing, product safety testing, software, usability studies, and risk management activities in conformance with Medical devices — Application of risk management to medical devices, ISO 14971, 2012 were reviewed and evaluated.

The candidate devices fall within the same range of equivalence for output energy characteristics and construction for meeting accepted safety standards for transcutaneous electrical nerve and muscle stimulators; and therefore, they do not raise new questions of safety.

Results confirmed that design and safety requirements were met, and that no new questions of safety or effectiveness were raised. This data was used to determine substantial equivalence.

Safety and Effectiveness

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

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

Conclusion

The Avazzia EZZI-LIFT device has intended use and technological characteristics that are substantially equivalent to the predicate devices.