February 10, 2025

Raja Trading Company, Inc.
℅ Yolando Smith
Smith Assoicates
1469 Harwell Ave
Crofton, Maryland 21114

Re: K243063
Trade/Device Name: Myolight Microcurrent Handpiece
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: January 15, 2025
Received: January 15, 2025

Dear Yolando Smith:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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.

Submission Number *(if known)*

K243063

Device Name

Myolight Microcurrent Handpiece

Indications for Use *(Describe)*

The device is indicated for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

510(k) Number: K243063

1. Date of Preparation

2/7/2025

2. Applicant

Name:	RAJA Trading Company Inc.
Address:	2801 Juniper Street, Suite 2, Fairfax, VA 22031
Contact Person:	Robert J. Adipietro
Title:	Vice President
Telephone:	561-868-4600
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3. Identification of the Proposed Device

Trade Name:	MyoLight Microcurrent Handpiece
Common Name:	Microcurrent Stimulator
Classification Name:	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Classification:	Class II
Product Code:	NFO
Regulation Number:	21 CFR 882.5890
Review Panel:	Neurology

Attachment	Regulation Name	Regulation No.	Product code	Class
MyoLight Microcurrent Handpieces	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	882.5890	NFO	2

4. Identification of Predicate Devices

Primary Predicate Device	Manufacturer	Trade Name	Product Code	510K Number
Aesthetic TENS Device	BTL Industries, Inc.	BTL-785BNF Handpiece	NFO	K232172
Reference Predicate Device #1	**Manufacturer**	**Trade Name**		**510K Number**
Aesthetic TENS Device	Salton, Inc.	Rejuvenique Facial Toning System	NFO	K011935
Reference Predicate Device #2	**Manufacturer**	**Trade Name**		**510K Number**
Aesthetic TENS Device	Avazzia, Inc.	EZZI-LIFT	NFO	K191951

5. Product Description

The subject device, the MyoLight Microcurrent Handpieces are intended to be used together with a main control unit that is equipped with a color touch screen that significantly facilitates the use of the device. There are two MyoLight Microcurrent Handpieces that connect to the main unit. The small handpiece (diameter: 3.9 cm, Length: 14 cm) is generally used on the face and the large handpiece (diameter: 6.2 cm, Length: 15 cm) is generally used on the body. The handpieces are different in dimensions but not function. The handpieces contain the electrodes that deliver microcurrent for aesthetic use.

The subject device is intended to be used together with a main control unit that is equipped with a color touch screen that significantly facilitates the use of the handpieces. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen of the device. During the therapy the device displays information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

The product is only sold to professionals licensed to administer the treatments including aestheticians, med spas, plastic surgeons and dermatologists and other licensed professionals. It is not intended to be sold to the consumer or for home use.

6. Indications for Use

The device is indicated for aesthetic use, including facial and neck or body skin stimulation.

7. Substantially Equivalent (SE) Comparison

Specifications	Subject Device	Primary Predicate Device	Reference Predicate Device # 1	Reference Predicate Device # 2
510(k) Number	K243063	K232172	K011935	K191951
Manufacturer	RAJA Trading Company	BTL Industries, Inc	Salton, Inc.	Avazzia, Inc.
Device Name	MyoLight Microcurrent Handpiece	BTL-785BNF Handpiece	Rejuvenique Facial Toning System	EZZI-LIFT
Classification & Subsequent Product Codes	NFO	NFO	NFO	NFO
Regulation Number	882.5890	882.5890	882.5890	882.5890
Classification Name:	Transcutaneous Electrical Never Stimulator for Pain Relief	Transcutaneous Electrical Never Stimulator for Pain Relief	Transcutaneous Electrical Never Stimulator for Pain Relief	Transcutaneous Electrical Never Stimulator for Pain Relief
Common Name	Esthetic TENS Device	Esthetic TENS Device	Esthetic TENS Device	Esthetic TENS Device
Indications for use	The device is indicated for aesthetic use including facial and neck or body skin stimulation.	The device is indicated for aesthetic use including facial and neck or body skin stimulation.	Indicates for Cosmetic Use	The Avazzia OTC TENS for aesthetics, model BEST-AVl™ : EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.

Specifications	Subject Device	Primary Predicate Device	Reference Predicate Device # 1	Reference Predicate Device # 2
Anatomic Sites	Face, Neck, and Body	Face, Neck, and Body	Face	Face, Neck, and Body
Principal of Operation	Handpieces with electrodes that deliver electrical stimulation attached to a main body that contains the power supplies, the microprocessor control unit, and the touch-screen user interface.	Handpieces with electrodes that deliver electrical stimulation attached to a main body that contains the power supplies, the microprocessor control unit, and the touch-screen user interface.	Face Mask with electrodes that fit over users face that delivers electrical stimulation connected to a control unit.	Handheld portable device with electrodes, batteries and user controls.
User Interface	LCD Touch Screen on main Control Unit with Power Source and Microprocessor controlled	LCD Touch Screen on main Control Unit with Power Source and Microprocessor controlled	Control Unit with Power Source and Microprocessor controlled.	LEDs and switches
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366	Not Available	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366
Compliance with 21 CFR 898	YES	YES	YES	YES
Power Sources	Mains Power 110 – 120, 220 - 240 VAC, 50- 60 Hz	Mains Power 100 – 240V, 50 – 60 Hz	9V battery	Two 1.5 V AA batteries
Patient leakage current: Normal Condition	Compliant with IEC 60601-1 leakage current requirements	Compliant with IEC 60601-1 leakage current requirements	Not Available	Compliant with IEC 60601-1 leakage current requirements
Method of Channel Isolation	Compliant with IEC 60601-1 isolation requirements	Compliant with IEC 60601-1 isolation requirements	Electrode Group selected by relays	Compliant with IEC 60601-1 isolation requirements
Synchronous or Alternating Output	Both	Both	Alternating	Not Available
Software / Firmware / Micro-Processor Control?	Yes	Yes	Yes	Yes
Number of Output Modes	1	1	1	4

Specifications	Subject Device	Primary Predicate Device	Reference Predicate Device # 1	Reference Predicate Device # 2
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage
Housing Materials and Constructions	Molded PC-ABS plastic material with screw assembly construction.	PCBs and leads inside plastic, or foam case housing.	ABS Plastic, latch assembly	PCBs inside plastic case housing
Energy Type	Electrical Stimulation	Electrical Stimulation	Electrical Stimulation	Electrical Stimulation
Voltage Current Level	Yes – Uncalibrated Knob	Yes	Yes – Uncalibrated Knob	Not Available
Handpiece Dimensions	Handpiece #1: 62mm x 147 mm Handpiece #2: 39mm x 139.5 mm	38.98” x 53.94” x 34.65”	4.5” X 3” X 1.25”	2.6" X 4.7" X 1.35"
Handpiece Weight	Handpiece #1: 1100 g Handpiece #2: 720 g	2500 g	80 grams	5.4 oz.
Recommended Treatment Time/ Timer range	20 Minutes Recommended Treatment Time	20 Minutes Timer range	20/16 minutes Timer Range	Not Available
Output Modes	1	1	1	4
Automatic Shut Off	YES	Unknown	YES	YES
Patient Contact	YES	YES	YES	YES
Contact Material	Stainless Steel 304 PMMA	Conductive Ink (Silver)	PCB Mask with Gold Plated Brass Electrodes	Stainless Steel 316
Waveform Shape	Pulsed Biphasic rectangular modulated by trapezoidal	Pulsed Biphasic rectangular modulated by trapezoidal	Pulsed Biphasic rectangular	Positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading
Max output voltage [V] (±20%) at 500 Ω 2,000 Ω 10,000 Ω	 30V @ 500 Ω 33V @ 1,000 Ω	BTL-785-2, -8, -9 Max. 48,5V @ 10 - 373 Ω 48,5V @ 500 Ω 48,5V @ 2,000 Ω 0 @ 10,000 Ω	 18V @ 500 Ω 24V @ 1,000 Ω	 42V @ 500 Ω

Specifications	Subject Device	Primary Predicate Device	Reference Predicate Device # 1	Reference Predicate Device # 2
	35V @ 10,000 Ω	BTL-785-1, -7 Max. 48,5V @ 10 - 757 Ω 48,5V @ 500 Ω 48,5V @ 2,000 Ω 0 @ 10,000 Ω	28V @ 10,000 Ω	122V @ 2,000 Ω 348V @ 10,000 Ω
Max output current (+/-20%) a 500 Ω 2,000 Ω 10,000 Ω	60 mA @ 500 Ω 33 mA @ 1000 Ω 3.5 mA @ 10,000 Ω	BTL-785-2, -8, -9 Max. 130 mA @ 10 - 373 Ohm 97 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω BTL-785-1, -7 Max. 64 mA @ 10 - 757 Ω 64 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω	37.6 mA @ 500 Ω 12.4 mA @ 1000 Ω 2.8 mA @ 10,000 Ω	Max. 0.5 mA 0.363 mA @ 500 Ω 0.117 mA @ 2000 Ω 0.038 mA @ 10000 Ω
Max current density at 500 Ω [µA/mm^2]	82 µA/mm^2	BTL-785-2 - 243 µA/mm^2 BTL-785-8 - 335 µA/mm^2 BTL-785-9 - 277 µA/mm^2 BTL-785-1 – 168 µA/mm^2 BTL-785-7 - 337 µA/mm^2	464 µA/ mm^2	Built-in, Y Brush: 8 µA/mm^2 Pencil: 190 µA/mm^2
Max average power density at 500 Ω [W/cm^2]	0.012W/ cm^2	BTL-785-2 – 0.047 W/cm^2 BTL-785-8 - 0.065 W/cm^2 BTL-785-9 - 0.054 W/cm^2 BTL-785-1 – 0.033 W/cm^2 BTL-785-7 - 0.065 W/cm^2	0.0023 W/ cm^2	Built-in, Y Brush: 0.0005 W/cm^2 Pencil: 0.0035 W/cm^2
Net Charge per pulse	0 µC (Pulse is biphasic symmetrical)	0 µC (Pulse is biphasic symmetrical)	0 µC	4 µC
Max phase charge per pulse at 500 Ω [µC]	23 µC	BTL-785-2, -8, -9 15 µC	11.3 µC	10 µC

Specifications	Subject Device	Primary Predicate Device	Reference Predicate Device # 1	Reference Predicate Device # 2
		BTL-785-1, -7 10 μC		
Duration of primary [μs] (depolarizing phase)	128 μs, 256 μs, 384 μs	80 μs	Not Available	500 μs
Pulse Duration [μs]	128 μs, 256 μs, 384 μs	160 μs	300 μs	1100 μs
Frequency [Hz]	1 ~ 63 Hz	250 Hz	8 Hz	15-121 Hz

Similarities
The subject device is similar to the predicate product in:

- same classification information,
- same indications and intended use,
- same principle of operation
- same performance effectiveness and performance safety as the primary predicate device.
- same waveform shape
- same maximum average power density
- substantially equivalent maximum output voltage
- substantially equivalent output current

Differences
The differences do not affect the performance and effectiveness of the subject device. Differences in Maximum Voltage, Maximum Current, Frequency, Pulse Duration, Phase Charge, and Current Density do not affect the performance and safety of the subject device.

Therefore, the MyoLight Microcurrent Handpiece device is substantially equivalent to the predicate device.

8. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2:2014/EN 60601-1-2:2015, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- 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.
- Biocompatibility Tests per ISO 10993 and FDA Guidance.
- Software Validation & Verification Test.
- Bench Testing to verify the performance.

9. Clinical Testing

Not Applicable

10. Conclusion

Based on the comparison and analysis above, the proposed subject device is Substantially Equivalent (SE) to the predicate device.