June 28, 2023

YA-MAN Ltd
% Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LPP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K220198
Trade/Device Name: Medi Lift PLUS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: June 26, 2023
Received: June 26, 2023

Dear Jonathan Kahan:

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,

Tushar Bansal -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220198

Device Name
Medi Lift PLUS

Indications for Use *(Describe)*
The Medi Lift PLUS is intended for facial stimulation and indicated for over-the-counter cosmetic use.

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

YA-MAN Ltd's Medi Lift PLUS

Submitter

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Date Prepared: June 28, 2023

Name of Device: Medi Lift PLUS

Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes

Regulatory Class: Class II

Product Code: NFO

Predicate Device

510(k) Number: K120511
Trade Name: Ageless Wonder Facial Muscle Stimulation System
Manufacturer: Leto Enterprise Ltd
Product Code: NFO

Reference Device

510(k) Number: K103031
Trade Name: BMR face
Manufacturer: Bio-Medical Research, Ltd.
Product Code: NFO

Device Description

The Medi Lift PLUS is composed of a mask made of silicone rubber which is worn on the lower part of the user's face, and covers the user's cheeks and nose. The mask contains two controllers with electrodes, which are attached to the mask. These controllers and electrodes deliver electrical pulses to stimulate facial muscles. The controllers are operated independently by pressing buttons on each controller. The controllers attached to the mask contain two charging pins which allows for the built-in Lithium-ion battery that powers the device to be charged using a USB charging cable and an adapter that is provided as part of the device. The device is not operated during charging.

Intended Use / Indications for Use

The Medi Lift PLUS is intended for facial stimulation and indicated for over-the-counter cosmetic use.

Summary of Technological Characteristics

The intended use of the Medi Lift PLUS is identical to that of the predicate device, namely both devices are indicated for over the counter facial stimulation, and use the same technology of energy delivered through electrodes placed on the user's face.

The output waveform of the Medi Lift PLUS is Symmetric Pulsed biphasic and quadphasic, and the maximum output voltage of the Medi Lift PLUS is in the range of the that of the predicate device. The maximum output current of the Medi Lift PLUS is higher than the predicate device, but that is lower than the reference device.

The differences regarding main output specifications between Medi Lift PLUS device and the predicate or reference devices do not raise new or different questions of safety and effectiveness.

A table comparing the key features of the subject and predicate devices is provided below.

Table 7-1: Comparison Table For Basic Technological Characteristics

Characteristics	**Medi Lift PLUS**	**Predicate Device Ageless Wonder (K120511)**	**Reference Device BMR face (K103031)**
Product code	NFO	NFO	NFO
Regulation Number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
OTC or Prescriptive use	OTC	OTC	OTC
Intended use	The Medi Lift PLUS is intended for facial stimulation and indicated for over-the-counter cosmetic use.	Ageless Wonder Facial Toning Device is intended for facial stimulation and indicated for over-the-counter cosmetic use.	BMR Face. Type 371/372, is a facial toning product which delivers electrical stimulation to the face for cosmetic use.
Intended anatomical position in the face	Cheeks	Cheeks (headset) /Forehead, Chin and jawline, under eye area (handheld)	Cheeks
Wearable or handheld	Wearable	Wearable and Handheld	Wearable
Operation of the device	A user attaches two controllers to the right and left sides of the silicone mask so that the silicone mask holds the controllers. The user moistens cheeks with tap water and then, wears the	A user attaches the conductive sponges onto the two application wands and wets the sponges. The wands are applied to the headset. The user fits the headset to the face. The wands with	A user attaches the gel pads to the two paddles of the headset and fits the headset to the face. The paddles with gel pads deliver electrical impulses from the controller to the face. The headset

Characteristics	Medi Lift PLUS	Predicate Device Ageless Wonder (K120511)	Reference Device BMR face (K103031)
	silicone mask which covers lower part of the user's face. The silicone mask is adjusted to positions of user's eyes, nose, and mouth. The user fixes the mask with a hook and loop fastener in the distal parts of the mask. The controllers have electrodes which deliver electrical impulses to the cheeks. Also, the controllers have +/ON button for turning on the device and increasing intensity and –/OFF button for turning off the device and decreasing intensity. The user operates the device using the controllers.	wet sponges deliver electrical impulses from the controller to the face. The headset is connected to the control unit which has ON/OFF button, increase or decrease intensity on both wands of the headset, mode button, and display. The user operates the device using the control unit. The user can hold the wands with the hands and place and operate the device on the forehead, the chin and jawline, and under eye area.	is connected with the control unit which has ON/OFF/pause button, increase or decrease intensity on the left and right sides of the headset, information button, program button and display. The user operates the device using the control unit.
Number of Controller (signal generator)	2	1	1
Conductive Media	Water	Water	N/A because the reference device contains gel pads.
Power source	One 3.7 V Lithium ion battery/one signal generator	Two of 1.5 V AAA battery	3.6V NiMH rechargeable battery pack
Patient Leakage Current	Protection method: Type BF applied part	Protection method: Type BF applied part	Not applicable, no line connection, no AC charger connection or operation. Connection method does not allow AC charger connection. Normal condition: 0µA Single fault condition: 0µA
Number of Output Modes	One treatment area / one mode	One treatment area/ one mode x 6 treatment areas	One treatment area/ Three treatment modes
Number of Output Channels	2/ one controller	1	2
Indicator display	LED indicator lights	LCD display	LCD display

Characteristics	Medi Lift PLUS	Predicate Device Ageless Wonder (K120511)	Reference Device BMR face (K103031)
Timer Range (minutes)	Fixed 10 minutes. The user cannot change the default setting.	5 – 20 minutes. The user can select the treatment time form 5, 10, 15, or 20 minutes.	20 minutes for program 1, 10 minutes for program 2, 20 minutes for program 3/ The user cannot change the default setting.
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5 ISO 10993-10	IEC60601-1 IEC 60601-2-10 IEC 60601-1-2 Battery charger IEC60950 and UL1950
Weight	28 g / one controller, Silicone mask 120 g: Total 176 g	90 g (including a headset)	63 g
Dimensions [W x H x D]	Controller 90 x 55x 20 (mm) Mask 615 x 170 (mm)	98.5x 53 x 27.5 (mm)	6.0 x 8.0 x 2.1 (cm)
Housing Materials and Construction	ABS	Unknown	ABS

The following **Table 7-2** shows the comparison between the output specification of the Medi Lift PLUS, the predicate and the reference devices.

Table 7-2 Comparison of The Output Specification

Specification	Medi Lift PLUS	Predicate Device Ageless Wonder (K120511)	Reference Device BMR Face (K103031)
Waveform	Symmetric Pulsed Biphasic and Quadphasic	Unknown	Pulsed, symmetric, biphasic
Shape	Rectangular pulses	Unknown	Rectangular, with interphase interval
Maximum Output Voltage	39.3 Vpp ＠500Ω (+/- 20%)	0 to 51V（0-1000Ω）	Output-Peak voltage 15.1 V@500Ω 60.6V@2kΩ 30.3 V@10kΩ (+/- 10%)
Maximum Output Current	3.22 mA@500Ω (+/- 20%)	0 to 43.2μA（0 to1000Ω）	Output-Peak current 30.2 mA@500Ω 30.3 mA@2kΩ 3.0 mA@10kΩ (+/- 10%)

Specification	Medi Lift PLUS	Predicate Device Ageless Wonder (K120511)	Reference Device BMR Face (K103031)
Pulse Width	152/168/192 µs ±10% (@2.5-100Hz), 52µs ±10%(@ 1kHz)	150 µs	300 µS max (both phase + 100 µS interphase delay)
Frequency (Hz)	2.5Hz, 5 Hz, 6Hz, 7Hz, 8Hz, 9Hz, 10 Hz, 20 Hz, 25 Hz, 33 Hz, 50 Hz, 66 Hz, 100Hz, 1 k Hz	Unknown	70Hz, 80Hz
For interferential modes only: - Beat Frequency (Hz)	NA	NA	NA
For multiphasic waveforms only: - Symmetrical phases?	Yes	Unknown	Yes
- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	38/42/48 µs ±10% (@2.5-100Hz), 26µs ±10%(@ 1kHz)	Unknown	80-100µS symmetrical
Net Charge (mC per pulse)	0	Unknown	0@500Ω Symmetric, biphasic and leading polarity alternates for each successive pulse
Maximum Phase Charge, (mC)	0.084µC@500Ω	Unknown	3.0 µC@500Ω
Maximum Current Density, (mA/cm²)	0.64 mA/cm²@500Ω =3.22 mA@1kHz / 5.04 cm² (area of a electrode. All 6 electrode of the device are the same size)	Unknown	0.4 mA/cm²@ 500Ω
Maximum Power Density, (W/cm²) The maximum power density should be less than 0.25 Watts/cm2 to reduce the risk of thermal burns.	$I^2 \times R = (0.00322)^2 \times 500 = 0.0052$ Watts = 5.2 mW 0.0052 /5.04 = 0.0010 W/ cm²	Unknown	0.34 mW/cm²@ 500Ω
ON Time (seconds)	0.2 to 16 seconds (Depending on the pattern of output and the intensity level)	Unknown	Unknown
OFF Time (seconds)	1 to 4 seconds (Depending on the pattern of output)	Unknown	Unknown

Performance Data

The Medi Lift PLUS device was assessed in accordance with the following standards:

- IEC60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)

- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

- IEC 60601-1-11: 2015, 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 60601-2-10:2012, AMD1:2016, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

- ISO10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

- Chemical characterization with targeted analysis for polycyclic aromatic hydrocarbons, according to ISO 10993-18:2020

- Tensile strength of the mask

- Electrical output of the Medi Lift PLUS

- Software verification and validation

Conclusions

The Medi Lift PLUS is as safe and effective as the predicate device. The Medi Lift PLUS has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the Medi Lift PLUS and its predicate device raise no new issues of safety or effectiveness. Thus, the Medi Lift PLUS is substantially equivalent to the predicate device.