



October 29, 2025

YA-MAN Ltd.
% Lina Kontos
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K250618

Trade/Device Name: Medi Lift Essential Eye Mask
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 30, 2025
Received: September 30, 2025

Dear Lina Kontos:

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,


Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Indications for Use

Submission Number (if known)

K250618

Device Name

Medi Lift Essential Eye Mask

Indications for Use (Describe)

The Medi Lift Essential Eye Mask 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's Medi Lift Essential Eye Mask
K250618

Submitter

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Contact Person: Jun Takada

Date Prepared: October 27, 2025

Name of Device: Medi Lift Essential Eye Mask

Common Name: Stimulator, transcutaneous electrical, aesthetic purposes

Regulatory Classification: Class II, 21 CFR 882.5890

Product Code: NFO (Stimulator, Transcutaneous Electrical, Aesthetic Purposes)

Predicate Devices

Primary Predicate Device

510(k) Number: K220198
Trade Name: Medi Lift PLUS
Manufacturer: YA-MAN Ltd.
Product Code: NFO

Secondary Predicate Device

510(k) Number: K120511
Trade Name: Ageless Wonder
Manufacturer: Leto Enterprises Incorporation
Product Code: NFO

Device Description

The Medi Lift Essential Eye Mask ("Medi Lift Eye") is composed of a mask made of silicone rubber which is worn on the upper part of the user's face, and covers the upper cheek and the periocular region outside the orbital rim. 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 mask also contains a heater to warm the upper cheek area for user relaxation, not for a medical purpose. The stimulation and heating functions are provided in separate modes and cannot be

used simultaneously. The controllers attached to the mask contain two charging pins which allow for the built-in Lithium-ion battery that powers the device to be charged using a USB charging cable that is provided as part of the device. The device is not operated during charging.

Intended Use/Indications for Use

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

Summary of Technological Characteristics

The Medi Lift Eye device achieves its intended use of facial stimulation by energy delivered through electrodes placed on the user’s face, exactly in the same manner as the predicate devices, Medi Lift Plus (K220198) and Ageless Wonder (K120511). The subject device is intended to stimulate the upper cheek and the periocular region outside the orbital rim, which is the same as the secondary predicate device, whereas the primary predicate device is intended to stimulate the cheeks only. Both Medi Lift Eye and the primary predicate device have a silicone mask as the set form factor, which standardizes the electrodes’ placement and procedures for use. The secondary predicate device’s eye-specific applicator is provided as a single-size electrode pad that is shaped to cover the intended treatment area. Both the primary predicate and subject device are powered by one rechargeable 3.7 V Lithium ion battery per signal generator, while the secondary predicate device is powered by non-rechargeable batteries.

The subject device is used with water or with an electroconductive gel provided with the device (Spectra 360 manufactured by Parker Laboratories, Inc.), depending on the user’s preference, while both predicate devices use water as the conductive media.

The Medi Lift Eye device also includes a heater to warm the upper cheek, while neither predicate device has a heater. This feature is provided for user relaxation only, not for a medical purpose. Therefore, the device’s therapeutic function (facial stimulation) is the same as the predicate devices.

Based on above, the differences between Medi Lift Eye device and the predicate devices do not raise new or different questions of safety or effectiveness. The table below provides a comparison of the technological characteristics for the subject device and the predicate device.

Table 1: Comparison of Technological Characteristics

	Subject Device: Medi Lift Eye (K250618)	Primary Predicate Device: Medi Lift Plus (K220198)	Secondary Predicate Device: Ageless Wonder (K120511)	Comparison between the Medi Lift Eye and predicate devices
Product code	NFO	NFO	NFO	Same
Regulation number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	Same
OTC or prescription	OTC	OTC	OTC	Same

	Subject Device: Medi Lift Eye (K250618)	Primary Predicate Device: Medi Lift Plus (K220198)	Secondary Predicate Device: Ageless Wonder (K120511)	Comparison between the Medi Lift Eye and predicate devices
Indications for use	The Medi Lift Eye is intended for facial stimulation and indicated for over-the-counter cosmetic 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.	Same
Intended anatomical position in the face	The upper cheek and the periocular region outside the orbital rim	Cheeks	(Under eye mode) The upper cheek and the outer side of the eye; handheld and placed by users	Same as the secondary predicate device
Warming feature	Yes, for user comfort in a separate mode from EMS treatment. The upper cheek is warmed by a film heater inside the electrode. Includes a thermal sensor to keep the electrode surface <40 °C.	No	No	Different, but does not raise different questions because the heater mode is not for medical purposes.
Wearable or handheld	Wearable	Wearable	Wearable and handheld (under eye mode uses the handheld unit, which is held in place during treatment)	Same as the primary predicate, similar to secondary predicate. Device is stationary during treatment.
Conductive media	Conductive gel or Water	Water	Water	Similar, subject device has gel as an additional option for users.
Number of controllers (signal generator)	2 (right and left)	2 (right and left)	1	Same as primary predicate, similar to secondary predicate (applied to one side of the face at a time).
Number of electrodes per controller	2	3	2 (under eye mode)	Same as secondary predicate; difference from primary predicate caused by

	Subject Device: Medi Lift Eye (K250618)	Primary Predicate Device: Medi Lift Plus (K220198)	Secondary Predicate Device: Ageless Wonder (K120511)	Comparison between the Medi Lift Eye and predicate devices
				different applied anatomic area.
Power source	One 3.7 V, 350 mAh Lithium ion battery per signal generator	One 3.7 V, 60 mAh Lithium ion battery per signal generator	Battery powered (two 1.5 V AAA batteries)	Similar, all are battery powered.
Patient leakage current	Protection method: Type BF applied part	Protection method: Type BF applied part	Protection method: Type BF applied part	Same
Number of output channels	1 per controller	2 per controller	1 per controller	Same as secondary predicate, similar to primary predicate
Indicator display	LED indicator lights for on/off status of the device and the heater, battery status during charging	LED indicator lights for on/off status, battery status during charging	LCD display for on/off status, low battery, voltage/current level	Similar, all indicate on/off status, battery status, and mode.
Timer range (minutes)	Fixed 10 minutes. The user cannot change the default setting.	Fixed 10 minutes. The user cannot change the default setting.	Options for 5, 10, 15, or 20 minutes	Same as the primary predicate
Weight	Controller: 32 g each Silicone mask: 109 g Total: 173 g	Controller: 28 g each Silicone mask: 120 g Total: 176 g	90 g total (including a headset)	Similar to the primary predicate
Dimensions [W x H x D]	Controller: 78 x 54 x 150 mm Mask: 620 x 230 mm	Controller: 90 x 55 x 20 mm Mask: 615 x 170 mm	98.5 x 53 x 27.5 mm	Similar to the primary predicate
EMS Specifications:				
Waveform	Symmetric Pulsed Quadphasic	Symmetric Pulsed Biphasic (1 kHz) and Quadphasic (under 1 kHz)	Symmetric Biphasic	Same as the primary predicate device for the applicable frequency range
Waveform shape	Sine pulses	Rectangular pulses	Sine pulses	Same as the secondary predicate
Maximum output voltage (at 500Ω)	45.6 Vpp ± 20%	39.3 Vpp ± 20%	Under eye mode: 4.08 - 29.6 V	Similar to primary predicate, within the range of the secondary predicate

	Subject Device: Medi Lift Eye (K250618)	Primary Predicate Device: Medi Lift Plus (K220198)	Secondary Predicate Device: Ageless Wonder (K120511)	Comparison between the Medi Lift Eye and predicate devices
Maximum output current (at 500Ω)	1.51 mA ± 20%	3.22 mA ± 20%	0 - 43.2 μA (0 to 1000Ω)	Similar, differences do not raise different questions
Pulse width	208 μs ± 10% (<100Hz), 288 μs ± 10% (100Hz)	152/168/192 μs ± 10% (2.5-100Hz) 52 μs ± 10% (1kHz)	150 μs	Similar, differences do not raise different questions
Frequency	5 Hz, 6 Hz, 7 Hz, 8 Hz, 9 Hz, 10 Hz, 20 Hz, 25 Hz, 33 Hz, 50 Hz, 100 Hz	2.5 Hz, 5 Hz, 6 Hz, 7 Hz, 8 Hz, 9 Hz, 10 Hz, 20 Hz, 25 Hz, 33 Hz, 50 Hz, 66 Hz, 100 Hz, 1 kHz	20 Hz	Similar, within the range of the primary and secondary predicate devices
For interferential modes only: - Beat frequency	NA	NA	Not publicly disclosed	Same
For multiphasic waveforms only: - Symmetrical phases?	Yes	Yes	Yes	Same
- Phase duration (state range, if applicable) (both phases, if asymmetrical)	52 μs ±10% (<100 Hz) 72 μs ±10% (100 Hz)	38/42/48 μs ±10% (2.5-100 Hz) 26 μs ±10% (1 kHz)	75 μs	Similar to primary and secondary predicates
Maximum phase charge (at 500Ω)	0.109 μC	0.084 μC	Not publicly disclosed	Similar to primary predicate
Maximum current density (at 500Ω)	0.70 mA/cm ² = 1.51 mA / 2.16 cm ² (area of smaller electrode)	0.64 mA/cm ² = 3.22 mA / 5.04 cm ² (area of an electrode; all are the same size)	Not publicly disclosed	Similar to primary predicate
Maximum power density (at 500Ω)	0.53 mW/cm ²	1.03 mW/cm ²	Not publicly disclosed	Similar to primary predicate

	Subject Device: Medi Lift Eye (K250618)	Primary Predicate Device: Medi Lift Plus (K220198)	Secondary Predicate Device: Ageless Wonder (K120511)	Comparison between the Medi Lift Eye and predicate devices
Burst mode (i.e., pulse trains)	None	None	Not publicly disclosed	Same
a. Pulses per burst	NA	NA	Not publicly disclosed	Same
b. Bursts per second	NA	NA	Not publicly disclosed	Same
c. Burst duration (seconds)	NA	NA	Not publicly disclosed	Same
d. Duty cycle [Line (b) x Line (c)]	NA	NA	Not publicly disclosed	Same
ON time (seconds)	0.05 to 4 seconds (Depending on the pattern of output and the intensity level)	0.2 to 16 seconds (Depending on the pattern of output and the intensity level)	Under eye mode: 3.174 seconds	Similar to primary predicate
OFF time (seconds)	0.35 to 2 seconds (Depending on the pattern of output)	1 to 4 seconds (Depending on the pattern of output)	Under eye mode: 1.148 seconds	Similar to primary predicate

Performance Data

The subject device was assessed in accordance with the following standards and performance tests:

- IEC 60601-1-2:Ed 4.1 2020, 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 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 62133-2 Edition 1.0 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
- IEC 60601-1-11: Ed. 2.1 2020, 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.
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation.
- Electrical output of the Medi Lift Essential Eye Mask
- Thermal testing of the electrodes
- Software verification and validation

Conclusions

In conclusion, the Medi Lift Eye is substantially equivalent to the identified predicate devices, Medi Lift PLUS (K220198) and Ageless Wonder (K120511), because they have identical indications for use and similar technological characteristics. The minor differences in technological characteristics and procedures for use do not raise different questions of safety or effectiveness, because they do not alter the fundamental technology, purpose or method of use of the Medi Lift Eye as compared to its predicates. In addition, testing of the Medi Lift Eye with acceptable scientific methods evaluated the effects of the minor technological differences and demonstrated that the subject device is as safe and effective as the predicates.