January 16, 2025

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

Re: K244048
Trade/Device Name: Medi Lift Mask
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 31, 2024
Received: December 31, 2024

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

for Heather Dean, Ph.D.
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.

510(k) Number *(if known)*
K244048

Device Name
Medi Lift Mask

Indications for Use *(Describe)*
The Medi Lift 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

K244048

YA-MAN Ltd.'s Medi Lift Mask

Submitter

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Tokyo, 1350016 JAPAN
Phone: +81-3-5665-7321
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Contact Person: Jun Takada

Date Prepared: December 31, 2024

Name of Device: Medi Lift Mask

Regulatory Classification: Class II, 21 CFR 882.5890

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

Predicate Device

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

Device Description

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

Summary of Technological Characteristics

The Medi Lift Mask is a modification to the previously cleared Medi Lift PLUS (K220198). The devices have the same intended use and indications for use, and the technological characteristics

of the Medi Lift Mask are nearly identical to that of the predicate device. The only difference is a change in the UV varnish material on the housing of the controllers.

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 Mask	**Predicate Device: Medi Lift PLUS (K220198)**
Product Code	NFO	NFO
Regulation Number	21 CFR 882.5890	21 CFR 882.5890
OTC or Prescription Use	OTC	OTC
Indications for Use	The Medi Lift Mask 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.
Intended Anatomical Position on the Face	Cheeks	Cheeks
Wearable or Handheld	Wearable	Wearable
Device Components	Silicone mask Controllers with electrodes Charging accessories (USB cable and AC adaptor)	Silicone mask Controllers with electrodes Charging accessories (USB cable and AC adaptor)
Number of Controllers (signal generators)	2	2
Number of Electrodes	3 per controller	3 per controller
Conductive Media	Water	Water
Power Source	Rechargeable 3.7 V Lithium-ion battery (1 per controller)	Rechargeable 3.7 V Lithium-ion battery (1 per controller)
Patient Leakage Current	Protection method: Type BF applied part	Protection method: Type BF applied part
Number of Output Modes	One treatment area / one mode	One treatment area / one mode
Number of Output Channels	2 per controller	2 per controller
Indicator Display	LED indicator lights	LED indicator lights
Timer Range	Fixed 10 minutes. The user cannot change the default setting.	Fixed 10 minutes. The user cannot change the default setting.
Weight	Controllers: 28 g each Silicone mask: 120 g Total: 176 g	Controllers: 28 g each Silicone mask: 120 g Total: 176 g
Dimensions [W x H x D]	Controllers: 90 x 55 x 20 mm each Mask: 615 x 170 mm	Controllers: 90 x 55x 20 mm each Mask: 615 x 170 mm
Electrode Area	5.04 cm^2 per electrode	5.04 cm^2 per electrode
Controller Housing Materials	ABS with a UV varnish	ABS with a UV varnish

Performance Data

To evaluate the modification, the following activities were performed:

- Risk analysis per ISO 14971:2019
- Biocompatibility evaluation per ISO 10993-1:2018 and testing of:
    - Cytotoxicity per ISO 10993-5:2009
    - Sensitization per ISO 10993-10:2021
    - Intracutaneous reactivity per ISO 10993-23:2021

Since there were no changes to the silicone mask, software, electrodes, or other electrical components of the device, the risk analysis determined that the prior tests performed for the predicate device regarding tensile strength, polycyclic aromatic hydrocarbons, software verification and validation, electrical stimulation outputs, electrical safety, and electromagnetic compatibility remained applicable.

Conclusions

As shown above, the Medi Lift Mask has the same intended use and indications for use as the predicate device, the Medi Lift PLUS (K220198). The new UV varnish on the controller housing does not raise different types of safety and effectiveness questions, and risk analysis and biocompatibility testing shows that the Medi Lift Mask is as safe and effective as the predicate device. Thus, the Medi Lift Mask is substantially equivalent.