November 13, 2025

ATOP Lighting Co., Ltd.
Tse Adrian
Registration Representative
4th. Floor, Building C, No. 3, Jian'an Road
Tangwei Community, Fuhai Street, Baoan District
Shenzhen City, Guangdong province 518110
China

Re: K252308
Trade/Device Name: LED Beauty Mask (RLBXX)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: July 24, 2025
Received: July 24, 2025

Dear Tse Adrian:

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,

Tanisha Hithe

Digitally signed by Tanisha Hithe
Date: 2025.11.13 20:20:39 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252308

Please provide the device trade name(s).

LED Beauty Mask (RLBXX)

Please provide your Indications for Use below.

The LED Beauty Mask is an over-the-counter device that is intended for use in the treatment of full-face wrinkles.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

 # K252308

Submitter Information

- Company: ATOP Lighting Co., Ltd.
- Address: 4th. Floor, Building C, No. 3, Jian'an Road, Tangwei Community, Fuhai Street, Baoan District, Shenzhen City
- Phone: +086-15915873605
- Contact: Tse Adrian, Registration representative
- Mail box: certificate@atophort.com

Device Information

- Trade/Device Name: LED Beauty Mask
- Model: RLBXX
- Common Name: Light-Based Over-The-Counter Wrinkle Reduction
- Classification regulation:
  Regulation number: 21 CFR 878.4810
  Regulation Description: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Review Panel: General & Plastic Surgery
- Product Code: OHS
- Device Class: Class II
- Submission number: # K252308

Subject Device Description

This product is based on low-energy red light therapy (LED Phototherapy), which achieves through precise wavelength control:

Wavelength selection: Using 630 red light and 830nm near-infrared light to treat wrinkle for 25-50 years women

The main body of the mask is made of medical-grade silicone, with a total weight of ≤300g, and an elastic headband, which can be worn for a long time without pressure.

Predicate Device Information

Predicate Device: LG PRA.L DERMA LED MASK

Manufacturer: LG Electronics, Inc.

510(k) number: K183671

Indication of use:

The LG PRA.L DERMA LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.

Indications for Use – Subject device

The LED Beauty Mask is an over-the-counter device that is intended for use in the treatment of full-face wrinkles.

Comparison of Technological Characteristics with the Predicate Device

Comparison Items	**Subject Device:** **LED Beauty Mask**	**Predicate Device 1:** **LG PRA.L DERMA LED MASK** **(K183671)**
Classification & Intended Use		
Classification	OHS Class II 21 CFR 878.4810	OHS Class II 21 CFR 878.4810
Intended use	The LED Beauty Mask is an over-the-counter device that is intended for use in the treatment of full-face wrinkles.	The LG PRA.L DERMA LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.
Location for use	Face	Face
Patient Population	For use in adults	For use in adults
OTC or prescription	Over-the-Counter	OTC
Classification name	Light based over the counter wrinkle reduction	Light based over the counter wrinkle reduction
Comparison Statement	The subject device enjoys the same classification and intended use with the predicate device.	

Technological Characteristics		
Principle / Method of Operation	The subject device adopts light emitting diodes	The LG PRA.L DERMA LED MASK is a device which

	(LED) in the red (630nm±5nm) + infrared (830nm±5nm) spectrum to irradiate on the face to realize its therapeutic effect.	allows emission of LED light in the RED (637 nm) and IR (854 nm) spectrum on to the face.
Wavelength	630nm, 830nm	637nm, 854nm
Material	Mask frame: Silicone Eye shade: Silicone Controller frame: PP Adaptor frame: PP	Mask frame: PC Eye frame: PP Eye shield: Silicone Viewing shield: ABS plastic Controller frame: PP Adaptor frame: PP Cradle frame: PP
Dimensions (mm)	Mask Frame: 391 x 207 x 6 Controller: 95 x 55 x 19 Adaptor: 56 x 35 x 21.5	LED Mask: 178.8 x 225 x 89 Controller: 40 x 30 x 110 Adaptor: 87x 44 x 28 Cradle: 180 x 229 x 167.8
Net weight	LED Mask: 164 g Controller: 66 g Adaptor: 60 g	LED Mask: 225 g Controller: 84 g Adaptor: 75 g Cradle: 380 g
Power supply	Input: 100 -240 V Frequency: 50 / 60 Hz Output: 5V 1A	Input: 100 -240 V Frequency: 50 / 60 Hz Output: 5V 1A
Light source	Light Emitting Diodes	Light Emitting Diodes

	(LED)	(LED)
Number of LEDs	Total 128 LEDs (64 of them are for 630 nm and the rest 64 of them are for 830 nm)	Total 160 LEDs (80 of them are for 637 nm and the rest 80 of them are for 854 nm)
LED power	25 mW/cm^2 total	25 mW/cm^2 total
Electronic power	Input: AC 100V ~ 240V Frequency: 50Hz/60Hz Output: 5V 1A	Input: AC 100V ~ 240V Frequency: 50Hz/60Hz Output: 5V 2A
Shape design	Mask type	Mask type
Battery	Lithium-ion	Lithium-ion
Treatment time	9 minutes daily 5 days per week for 8 weeks	9 minutes daily 5 days per week for 8 weeks
Comparison statement	The subject device has almost the same technological characteristics with the predicate device, and their slight difference in wavelength, material and Dimensions will not affect the core usage of the devices or validated by relevant standard evaluation or not bringing new safety and effectiveness concerns, thus will not affecting the substantial equivalence comparison. their differences are not affecting the core usage of the devices The efficiency of the subject device was able to reach an equivalence level of the predicate device.	

Patient-Contacting Materials	Silicone rubber	Not know	**Difference**
Electrical Safety	Verified according	IEC 60601-1	Identical

	to IEC 60601-1		
EMC	Verified according to IEC 60601-1-2	IEC 60601-1-2	Identical
Biocompatibility	Verified according to ISO 10993-5 and ISO 10993-10	Not know	**Difference**
Comparison Statement	The substantial equivalence of the subject device has been evaluated according to the FDA-recognized standards.		

5.6.1 Comparison summary

First, the subject device enjoys identical classification and intended use with the predicate device, which forms the foundation of their substantial equivalence.

Secondly, most technological characteristics have substantial equivalence differences is below:

Difference item
Principle / Method of Operation
Wavelength
Material
Dimensions
Net weight
Number of LEDs
Patient-Contacting Materials
Biocompatibility

Discussion of Tests Performed

1. Clinical Test

Clinical testing was not performed for the subject device as part of the submission.

2. Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure substantial equivalence:

	Standard Designation Number	Title of Standard
Electrical Safety	IEC 60601-1: 2020	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility	IEC 60601-1-2: 2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
Home environment use requirement	IEC 60601-1-11: 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
Biocompatibility	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: Test for skin sensitization
	ISO 10993-23: 2021	Biological evaluation of medical devices—Part 23: Tests for irritation

Conclusion

From the above analysis, it is proper to conclude that the subject device will be as safe and effective for usage as the listed predicate devices, K183671 that have already been on the U.S. market.

Date the Summary was prepared:

Oct. 08, 2025