July 19, 2022

Hunan Guangye Biotechnology Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K221151
Trade/Device Name: Beauty LED Mask, Model: KFB265
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, OLP
Dated: April 8, 2022
Received: April 20, 2022

Dear Tracy Che:

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,

Jianting Wang
Acting 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

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)*
K221151

Device Name
Beauty LED Mask, Model: KFB265

Indications for Use *(Describe)*
The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.

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" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Hunan Guangye Biotechnology Co., Ltd.
Address:	Room 701, Jinhong Park Incubation Building, No.229, Tongzipo West Road, High-tech Development Zone, Changsha City
Contact person:	Eileen Li
Phone number:	+86-0755-89373426
Fax number:	+86-0755-89373426
Email:	412904775@qq.com
Date of summary prepared:	2022-7-15

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	Beauty LED Mask/Model: KFB265
Common name:	Over-The-Counter Powered Light Based Laser For Acne; Light Based Over The Counter Wrinkle Reduction
Regulation number:	21 CFR 878.4810
Product code:	OHS, OLP
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate and reference device

- **Predicate device**

Sponsor	LG Electronics, Inc.
Device Name and Model	LG PRA.L DERMA LED MASK
510(k) Number	K183671
Product Code	OHS
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device**

Sponsor	Galactic Beauty, LLC
Device Name and Model	MMSphere™

510(k) Number	K190443
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

The Beauty LED Mask adopts light emitting diodes (LED) in the red (637nm ± 5nm) + infrared (854nm ± 5nm) and blue (465 ± 5nm) spectrum to irradiate on the face to realize its therapeutic effect. The Beauty LED Mask adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller is connected to the main unit to control the device, such as turn on/off the device, switch mode (LED color). Power adapter is provided to charge the battery contained in the controller. To use the device, user should place the mask over the face and use the controller to operate. The device will automatically turn off after each treatment. To prevent irradiation of LED lights to eyes during the treatment, Beauty LED Mask has incorporated protective eye-shield which blocks light energy from LEDs.

(6) Indications for use:

The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Beauty LED Mask	ABS, Silicone	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Subject device	Predicate device	Reference device	Remark
Trade name	Beauty LED Mask/ Model: KFB265	LG PRA.L DERMA LED MASK	MMSphere™	/
510 (k) number	Applying	K183671	K190443	/
Manufacturer	Hunan Guangye Biotechnology Co., Ltd.	LG Electronics, Inc.	Galactic Beauty, LLC	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Classification name	Light Based Over The Counter Wrinkle and	Light Based Over The Counter Wrinkle	OTC Powered Light for Wrinkle Reduction and	Same

	Acne Reduction	Reduction	Acne	
Product code	OHS, OLP	OHS	OHS, OLP	Same
Class	II	II	II	Same
Indications for use/ Intended use	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	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.	MMSphereTM Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphereTM is designed to be used for 20 minute treatments three to seven times per week.	Similar
Location for use	Face	Face	Face	Same
OTC or prescription	OTC	OTC	OTC	Same
Power supply	Input: 100 -240 V ~ 50 / 60 Hz Output: 5V 1A	Input: AC 100V ~ 240V Frequency: 50Hz/ 60Hz Output: 5V 2A	/	Different **Note 1**
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	Red (637nm±5nm) and IR (854nm±5nm); Blue (465±5nm)	RED (637nm) and IR (854nm)	465nm 605nm 625nm	Similar
LED power	Red+IR: 25.5mW/cm^2 Blue: 1.36mW/cm^2	Red+IR: 25mW/cm^2	Red: 2.45mW/cm^2 Blue: 1.33mW/cm^2	Similar
Treatment time	10min each time	9 minutes daily 5 days per week for 8 weeks	20mins/day, 120 days	Similar
Mask design	Yes	Yes	Handheld or placed on a countertop	Same
Dimensions (mm)	LED Mask: Approximately 183 mm x 238 mm x 98 mm Controller: 100mm x 50 mm x 21.5 mm	LED Mask: 180 x 214.5 x 92.4 Controller: 41 x 31 x 103	/	Different **Note 2**

Weight	245g	LED Mask: 207 g Controller: 82 g Adaptor: 75 g Cradle: 375 g	/	Different **Note 2**
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 62471-1	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Same

Comparison in details:

Note 1:

The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has passed IEC62133-2 test and the power adapter has been assessed for electrical safety along with the main unit, so this difference should not raise any safety/effectiveness questions.

Note 2:

Although the appearance, weight and dimensions are different between the subject and predicate device, these differences are insignificant and do not raise any safety/effectiveness problems.

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the Beauty LED Mask meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- ANSI AAMI ES 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11, 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 60601-2-57, Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

- IEC 62471, Photobiological safety of lamps and lamp systems
- IEC 62133-2, 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

The device has been tested for biocompatibility, it complies with the following standards.

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Beauty LED Mask is found to be substantially equivalent to the predicate device, K183671, LG PRA.L DERMA LED MASK.