May 5, 2023

Shenzhen SUNGPO HI-TECH Electronic Co., Ltd
% Rain Yip
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 ZhenYe International Center, No. 3101-90
Qianhai Road, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K230351
Trade/Device Name: LED Facial Mask
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: January 16, 2023
Received: February 9, 2023

Dear Rain Yip:

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,

Colin K. Chen -S

for

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)*
/

Device Name
LED Facial Mask, Model(s): MZ-01, NEWKEY-01, SP-FM-01

Indications for Use *(Describe)*
LED Facial Mask is an over the counter device that 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.

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510(k) Summary
K230351

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2023-01-16

I. Submitter

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II. Device

Name of Device: LED Facial Mask
Model(s): MZ-01, NEWKEY-01, SP-FM-01
Classification name: Light Based Over The Counter Wrinkle and Acne Reduction
Common Name: Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based For Acne
Regulatory Class: II
Product Code: OHS, OLP
Review Panel: General & Plastic Surgery
Regulation Number: 21 CFR 878.4810

III. Predicate Device

Predicate device	Predicate device	Reference device #1	Reference device #2
510(k) number	K220168	K203271	K190443
Sponsor	Shenzhen Kaiyan Medical Co Ltd	Shenzhen Kaiyan Medical CO LTD	Galactic Beauty, LLC
Device name and model	Skin Care Beauty Mask /MJ-06	Aduro light therapy Handheld/HD-03A	MMSphere™
Product code	OHS, OLP	OHS, OLP	OHS, OLP
Approval date	May 17, 2022	July 21, 2021	June 24, 2019

IV. Device Description

The LED Facial Mask is an over-the-counter, facemask-shaped design light emitting diode (LED) device that emits light energy in the red, blue, and amber spectrum for the treatment of wrinkles

or mild to moderate inflammatory acne on the face. The device consists of a mask body unit, controller, and AC adapter. The mask body unit contains light emitting diodes (LEDs) that emit visible red light (650nm+/-5nm), amber light (605nm+/-5nm), or blue light (465nm+/-5nm) to help reduce the appearance of wrinkles or mild to moderate acne. A controller is connected to the mask body unit to control the device, such as turn on/off the device, switch LED color output. An AC adapter is used to power the device. To use the device, user should place the mask body unit over the face and use the controller to operate. The device will automatically turn off after each treatment.

The LED Facial Mask includes MZ-01, NEWKEY-01, and SP-FM-01 models. Their intended use, performance, structure design, and operation are identical, with the difference being the product appearance, but these differences do not affect or change the intended use of the device.

V. Indications for Use

LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.

VI. Comparison of Technological Characteristics With the Predicate Device

Compare with predicate devices, the subject device LED Facial Mask is very similar to or in the same design principle, intended use, functions, materials, and the applicable standards. The differences between subject device and the predicate devices do not raise new questions of safety or effectiveness.

Comparison Elements	**Subject Device**	**Predicate device**	**Reference device #1**	**Reference device #2**
Trade name	LED Facial Mask/ MZ-01, NEWKEY-01, SP-FM-01	Skin Care Beauty Mask /MJ-06	Aduro light therapy Handheld/HD-03A	MMSphere™
510(k) number	K230351	K220168	K203271	K190443
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP
Classification name	Light Based Over The Counter Wrinkle and Acne Reduction	Light Based Over The Counter Wrinkle Reduction (OHS) Over-The-Counter Powered Light Based Laser For Acne (OLP)	Light Based Over The Counter Wrinkle and Acne Reduction	Light Based Over The Counter Acne and Wrinkle Reduction
Indication for use/Intended use	LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate	The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically	The Aduro light therapy Handheld (Model: HD-03A), the red light is intended for the treatment of periorbital	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum,

Comparison Elements	**Subject Device**	**Predicate device**	**Reference device #1**	**Reference device #2**
	acne.	indicated to treat full face wrinkles and/or mild to moderate acne.	wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.
Location for use	Face	Face	Face	Face
Treatment time	10 minutes/day, 3 times per week	5 or 10 minutes/day, 3 times per week	3-5 minutes on each treatment area. For best results 3-5 times per week with 2 day rest.	20mins/day, 120days
Environment for use	OTC	OTC	OTC	OTC
Power supply	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Adapter: Input: 100-240Va.c., 50/60Hz, 0.5A Output: 5.0Vd.c., 2.0A	2600mAh, 3.7V Li battery	Not publicly available
Irradiance source	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)
LED Wavelengths	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	Blue: 465nm±10nm Red: 640nm±10nm	Blue: 415nm±10nm Red: 630nm±10nm IR: 850nm	Amber: 605nm Red: 625nm Blue: 465nm
LED Power density	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2	Blue: 30mW/cm^2 Red: 30mW/cm^2	Blue: 20~65mW/cm^2 Red: 40~80mW/cm^2	Blue: 1.33mW/cm^2 Red: 2.45mW/cm^2
Material of device and construction	ABS and PC plastic	Not publicly available	ABS plastic	Not publicly available
Biocompatibility feature	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	Comply with ISO10993-5 and ISO10993-10

Comparison Elements	**Subject Device**	**Predicate device**	**Reference device #1**	**Reference device #2**
Compliance with voluntary standards	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471	Not publicly available	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the LED Facial Mask is ABS and PC plastic and performed the biocompatibility evaluation in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document issued on Sep. 4, 2020", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5 Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and Eye Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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 source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

3) Eye Safety

- IEC 62471 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***moderate level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Summary

Based on the above performance as documented in this application, the LED Facial Mask was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the LED Facial Mask is to be concluded substantial equivalent to its predicate device.