December 20, 2024

Shenzhen Siken 3D Technology Development Co., Ltd.
% Huang Bing
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K243040
Trade/Device Name: LED Light Therapy Mask (SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002, SKB-2418)
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: September 26, 2024
Received: September 27, 2024

Dear Huang Bing:

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2024.12.20 15:18:49 -05'00'

for 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

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)*
K243040

Device Name
LED Light Therapy Mask/Model: SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418

Indications for Use *(Describe)*
LED Light Therapy 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K243040 - 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:	Shenzhen Siken 3D Technology Development Co., Ltd.
Address:	4th Building,No.33 Left East Avenue,Songgang, Bao'an District, Shenzhen, Guangdong, China
Contact person:	Jing Quan Liu
Phone number:	+86-0755-27697523
Fax number:	+86-0755-27697523
Email:	1550420556@qq.com
Date of summary prepared:	2024-9-27

(2) Reason for the submission

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

(3) Proprietary name of the device

Trade name/model:	LED Light Therapy Mask/Model: SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418
Common name:	Light Based Over The Counter Wrinkle Reduction(OHS) Over-The-Counter Powered Light Based Laser For Acne(OLP)
Regulation number:	21 CRF 878.4810
Product code:	OHS, OLP
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate and reference device

- **Predicate device 1**

Sponsor	Hunan Guangye Biotechnology Co., Ltd.
Device Name and Model	Beauty LED Mask/ Mode: KFB265
510(k) Number	K221151
Product Code	OHS, OLP,
Regulation Number	21 CFR 878.4810
Regulation Class	Class II

- **Predicate device 2**

Sponsor	Shenzhen SUNGPO HI-TECH Electronic Co., Ltd
Device Name and Model	LED Facial Mask
510(k) Number	K230351
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	Class II

- **Reference device 1**

Sponsor	Guangdong Newdermo Biotech Co.,Ltd
Device Name and Model	LED light therapy mask (FM-01, FM-02, FM-03)
510(k) Number	K223544
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.550
Regulation Class	Class II

- **Reference device 2**

Sponsor	NIGOBO HESI ELECTRIC CO., LTD
Device Name and Model	LED FACIAL LIGHT THERAPY MASK(Model:HK207)
510(k) Number	K200983
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500
Regulation Class	Class II

(5) Description/ Design of device:

The LED Light Therapy Mask adopts light emitting diodes (LED) in the red (620nm±10nm), blue (460±10nm) and infrared (850nm±10nm) spectrum to irradiate on the face to realize its therapeutic effect. The LED Light Therapy Mask adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller (Only for SKB-2318L,SKB-2318P,SKB-2318PRO, IN-FM002,SKB-2418) is connected to the main unit to control the device, such as turn on/off the device, switch mode (LED color). 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, LED Light Therapy Mask has incorporated protective eye-shield which blocks light energy from LEDs.

(6) Indications for use:

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

(7) Materials

Component	Material of Component	Body Contact Category	Contact Duration

name			
LED light therapy mask	ABS, Silicone， Strap	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:

The LED Light Therapy Mask has the same intended use as the predicate. The technological characteristics such as wavelength and LED Power, are similar to the predicate device and reference devices. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use.

Therefore, the LED Light Therapy Mask may be found substantially equivalent to its predicate device and reference devices.

Item	Subject device	Predicate device 1	Predicate device 2	Reference device 1	Reference device 2	Remark
Trade name	LED light therapy mask	Beauty LED Mask/Model: KFB265	LED Facial Mask, Model(s):MZ-01, NEWKEY-01, SP-FM-01	LED light therapy mask	LED FACIAL LIGHT THERAPY MASK(Model:HK207)	/
510 (k) number	Applying	K221151	K230351	K223544	K200983	/
Manufacturer	Shenzhen Siken 3D Technology Development Co., Ltd.	Hunan Guangye Biotechnology Co., Ltd.	Shenzhen SUNGPO HI-TECH Electronic Co., Ltd	Guangdong Newdermo Biotech Co.,Ltd	NIGOBO HESI ELECTRIC CO., LTD	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	Same
Regulation Name	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 Wrinkle and Acne Reduction	Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For	Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For	Same

				Acne(OLP)；Infrared,Therapeutic Heating(ILY)	Acne(OLP)；Infrared,Therapeutic Heating(ILY)	
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS, OLP, ILY	Same
Class	II	II	II	II	II	Same
Indications for use/ Intended use	LED Light Therapy Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	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.	Red light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood	The LED FACIAL LIGHT THERAPY MASK(Model:HK207) is intended to: The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. The device emitting energy in the red and infrared spectrum is intended for treatment of full-face wrinkles.	Same

				circulation. Mixed light: Treatment of mild to moderate inflammatory acne.		
Location for use	Face	Face	Face	Face and body	Entire Face and body	Same
OTC or prescription	OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input: AC 100-240V 50-60Hz 0.3A Output: DC 5V 1A 3.7V 650mAh Li-ion Battery 3.7V1000mAh Li-ion Battery	Input:100-240V ~50/60 Hz Frequency: 50Hz/60Hz Output: 5V 2A	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: 100-240 V~, 50/60 Hz, 0.25 A Output: DC 5 V, 500 mA	Input:100-240Vac, 2.0A, 50/60Hz	Different **Note 1**
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LEDs)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS: Blue: 460nm±10nm Red: 620nm±10nm SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2	Red (637nm ± 5nm) and IR (854nm±5nm); Blue (465±5nm)	Blue:465nm±5nm Red: 625nm±5nm Amber: 605nm ± 5nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	465nm,640nm,880nm	Similar

	418: Blue: 460nm±10nm Red: 620nm±10nm Infrared: 850nm±10nm					
LED Intensity	SKB-1818P: Mode 1: Red: 5.5mW/cm^2 Mode 2: Blue: 9mW/cm^2 SKB-1918: Mode 1: Red: 5mW/cm^2 Mode 2: Blue: 6mW/cm^2 SKB-1918P： Mode 1: Red: 6mW/cm^2 Mode 2: Blue: 6.5mW/cm^2 SKB-1918PLUS： Mode 1: Red: 3.5mW/cm^2 Mode 2: Blue: 4.0mW/cm^2 SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418: Mode 1: Red： 3.5～10mW/cm^2 Mode 2: Blue： 2.5～8mW/cm^2	Red+IR:25.5mW/cm^2 Blue: 1.36mW/cm^2	Blue:15-63mW/cm^2 Red:31-72mW/cm^2	Red light: 2.0~3.0 mW/cm^2 Blue light:2.0~4.0 mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	6.5mW/cm^2	Different **Note 2**

	Mode 3: Red+Infrared Light：6～27mW/cm^2					
Treatment time	It is recommended to use it for 10 minutes a day, 3 times per week.	10min each time	10 minutes/day, 3 times per week	Manual Mode: 15minutes each time. Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2treatment a week once the results shown.	3 times a week for 30min. 4 weeks	same
Dimensions (mm)	Model SKB-1818P,SKB-1918, SKB-1918P: 194*170*131mm Model SKB-1918PLUS: 217*152*173mm SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418：411*195*4mm	LED Mask: Approximately 183mm x 238mm x 98mm Controller: 100mm x 50mm x 21.5mm	Not publicly available	FM-01: 207*277*43mm, FM-02: 198*383*33.5mm, FM-03: 237.5*108*8.1mm	Not publicly available	/
Weight	Model SKB-1818P,SKB-1918, SKB-1918P: 67g		Not publicly available	Not publicly available	Not publicly available	/

	Model SKB-1918PLUS: 70g SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418：161g					
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471 IEC 62133-2	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 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 60601-1-11	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5, ISO 10993-10 and ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Complied with ISO 10993-1, 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 of devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.

Note 2:

The LED Intensity of these devices are different, and the subject device has an LED intensity between Predicate device and Reference device. And has passed IEC60601-2-57 test, the slight difference will not raise safety and effective issue.

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to

the product come into conclusion.

(9) Non-clinical studies and tests performed:

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

1) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, 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, cosmetic and aesthetic use
- 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

2) Eye Safety

- IEC 62471 Photobiological safety of lamps and lamp systems

3) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the subject device was conducted 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”, as recognized by FDA. The following testing was performed to, and passed, including:

- 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 skin irritation

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 LED Light Therapy Mask is found to be substantially equivalent to the Predicate devices.