May 17, 2022

Shenzhen Kaiyan Medical Co Ltd
Alain Dijkstra
CEO
40A Fuxin Road Fuyong Subdistrict BaoAn District,
Shenzhen, Guangdong 518101
China

Re: K220168
Trade/Device Name: Skin Care Beauty Mask (Model: MJ-06)
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 17, 2022
Received: January 20, 2022

Dear Alain Dijkstra:

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,

Purva Pandya
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)*
K220168

Device Name
Skin Care Beauty Mask (Model: MJ-06)

Indications for Use *(Describe)*
The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or 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.

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510(k) Summary of K220168

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

1. Submitter's Information

Company Name: SHENZHEN KAIYAN MEDICAL CO LTD
Address: 40A Fuxin Road Fuyong Subdistrict BaoAn District Shenzhen, Guangdong, China
Contact Person (including title): Alain Dijkstra (CEO)
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E-mail: regulation@kaiyanmedical.com

Distributor

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Application Correspondent:

Contact Person: Alain Dijkstra
Company: SHENZHEN KAIYAN MEDICAL CO LTD
Address: 40A Fuxin Road Fuyong Subdistrict BaoAn District Shenzhen, Guangdong, China
Tel: +86 755 82129361
Email: regulation@kaiyanmedical.com

2. Subject Device Information

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
Trade Name: Skin Care Beauty Mask
Model Name: MJ-06
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulatory Class: II

3. Predicate Device Information

Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD

Trade Name: Aduro Light Beauty Mask, Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
510(K) Number: K202390
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulation Class: II

4. Device Description

The Skin Care Beauty Mask (Model: MJ-06) is a facemask-shaped device, which makes use of specific light spectral characteristics and directly applies light onto the face skin surface. The Skin Care Beauty Mask can emit two different kinds of wavelengths. The blue light (465nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. Red light (640nm) is intended to improve the appearance of wrinkles. There are 150 LED lights with a center wavelength of 465nm and 150 LED lights with a center wavelength of 640nm, and the energy provided by each mode is 30mw/cm2 . The user wears the mask on their face for the treatment, and the device will shut down automatically after finishing a 5-minute treatment or 10-minute treatment selected.

5. Intended Use / Indications for Use

The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.

6. Test Summary

Skin Care Beauty Mask (Model: MJ-06) has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Date
ANSI AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	07/09/2014

Standards No.	Standard Title	Version	Date
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	Edition 2.0 2015-01	06/27/2016
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	Edition 1.0 2011-01	03/16/2012
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	Edition 4.0 2014-02	09/17/2018
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	12/23/2016
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition 2010-08-01	07/26/2016

7. Comparison to predicate device and conclusion

The subject device is very similar in design principle, indications for use, functions, materials, and applicable performance, when compared to the above models of the K202390 predicate. Differences

between the subject device and predicate do not raise new types of questions with regard to the safety and effectiveness of the subject device for the proposed indications for use.

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD	SHENZHEN KAIYAN MEDICAL CO LTD	--
Trade Name	Skin Care Beauty Mask	Aduro Light Beauty Mask	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)	Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based OverThe Counter Wrinkle Reduction (OHS)	--
510(k) Number	K220168	K202390	--
Product Code	OHS, OLP	OHS, OLP	SE
Intended Use / Indications for Use	The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.	For MK-66O, MK-66USBO, MK-02O: The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.	SE
Wavelengths	Red: 640nm±10nm Blue: 465nm±10nm	Red: 640nm±10nm Blue: 465nm±10nm	SE
Power supply	Adapter: Input: 100-240Va.c., 50/60Hz, 0.5A Output: 5.0Vd.c., 2.0A	For model MK-66O, MK-66USBO: 3.7Vdc 2600mAh Lithium battery Adapter for charging only: Input: 100- 240Vac; Output: 5Vdc, 2A. For model MK-02O: 3.7Vdc 2600mAh Lithium battery	SE
Irradiance source	LEDs	LEDs	SE
Treatment time	5 or 10 minutes/day, 3 times per	10minutes/day, 3 times per week	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
	week		
Power Density (mw/cm^2)	$30mW/cm^2$	$30mW/cm^2$	SE
Location for Use	Face	Face	SE
Environment of Use	OTC	OTC	SE
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IE C60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IE C60601-1-11 IEC 60601-2-57	SE
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	SE

8. Conclusion:

The proposed device utilizes the same technological characteristics as the above listed model configurations of K202390, and is also for use in the treatment of mild to moderate acne and treatment of wrinkles. After an analysis of the proposed device's design, functionality, safety, materials, and performance testing results, the sponsor believes that the device's technology does not raise new types of questions regarding safety and efficacy of the subject device for the proposed indications, and performance testing supports that the device can be used safely and effectively. The subject device Skin Care Beauty Mask (Model: MJ-06) is considered to substantially equivalent to the above-specified devices of K202390.

9. Date prepared: May 2022