January 4, 2024

Shenzhen Kaiyan Medical Equipment Co., Ltd
Alain Dijkstra, General Manager
Building#3 and Building#5, 40th of Fuxin Street
Huaide Community Fuyong Town, Baoan District
Shenzhen, Guangdong 510530, China

Re: K233556
Trade/Device Name: LED Eye mask (EY-20R, A20, EY-20N)
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: November 2, 2023
Received: November 6, 2023

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 (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.

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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2024.01.04 15:15:05 -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.

Submission Number *(if known)*

K233556

Device Name

LED Eye mask (EY-20R, A20, EY-20N)

Indications for Use *(Describe)*

The LED Eye mask (Model: EY-20R, 20A, EY-20N) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

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 of K233556

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Contact Person (including title): Alain Dijkstra (Manager)
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Application Correspondent:

Contact Person: Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

2. Subject Device Information:

Trade Name: LED Eye Mask, model: EY-20R, A20, EY-20N
Classification Name: Light based OTC for winkle reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device (K221444)
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED Eye Perfector, model: EY-36A, EY-36B
Classification Name: Light based over the counter wrinkle reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810

4. Device Description

The LED Eye Mask, model: EY-20R, A20, EY-20N is an over-the-counter light-emitting diode (LED) device that emits energy for dermatology to treat wrinkles within the periorbital region. The device uses four types of LEDs is 605nm, 633nm, 660nm, 830nm. The LED Eye Mask components contain the main unit, USB cable cord and velcro straps and removable eye protection. There is a total of 40 LEDs to provide a power intensity of about 65 mW/cm^2. The device has only one button to turn on/off.
The user wears the device on their eye area for the treatment, and the device will shut down automatically

after a 3-minute after finishing treatment.
There are no differences between the three models other than the appearance.

5. Intended Use / Indications for Use

The LED Eye Mask (Model: EY-20R, A20, EY-20N) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

6. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device	Predicate device (K221444)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	--
Trade Name	LED Eye mask	LED Eye Perfector	
Model	EY-20R, A20, EY-20N	EY-36A, EY-36B	
510 (K) Number	Applying	K221444	--
Classification Name	Light Based Over-The Counter Wrinkle Reduction	Light Based Over-The Counter Wrinkle Reduction	--
Regulation Class	Class II	Class II	Same
Product Code	OHS	OHS	Same
Indications for Use / Intended use	The LED Eye mask (Model: EY-20R, A20, EY-20N) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	The LED Eye Perfector (Model: EY-36A, EY 36B) is an Over-the Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	Same
Power Source	Main unit: 3.7V, 300mAh lithium battery, 1.11Wh Adapter Input: 100 - 240Va.c., 50/60Hz Adapter Output: 5Vd.c, 2A	Main unit: 3.7V, 420mAh lithium battery, 1.55Wh Adapter Input: 100 - 240Va.c., 50/60Hz Adapter Output: 5Vd.c, 1A	Different, note 1
Wavelengths	605nm, 633nm, 660nm, 830nm	EY-36A: 605nm, 633nm, 660nm, 830nm EY-36B: 605nm, 625nm, 660nm, 880nm	Same
Mode	On/Off	On/Off	Same
Irradiance source	LED	LED	Same
Visiblle light LEDs	Yes	Yes	Same
Treatment Area	36.5cm^2	40cm^2	Similar, note 2
LED number	605nm: 20 633nm: 20 660nm: 20 830nm: 20 Total: 40 (Double lamp beads)	605nm: 20 633nm: 20 660nm: 20 830nm: 20 Total: 40 (Double lamp beads)	Same
Power flux (mW/cm^2)	605nm: 26.2±3	605nm: 24.5±3	Similar, note

Elements of Comparison	Subject device	Predicate device (K221444)	Remark
	633nm: 13.8±3 660nm: 20.3±3 830nm: 8.5±3 Total: 65	633nm: 16.2±3 660nm: 18.2±3 830nm: 6.7±3 Total: 65	2
LED distribution	Uniform distribution	Uniform distribution	Same
Treatment Time	3minutes per treatment	3minutes per treatment	Same
Target Population	Individuals with wrinkles on their face within the periorbital region.	Individuals with wrinkles on their face within the periorbital region.	Same
Location for USE	OTC	OTC	Same
EMC	IEC60601-1-2	IEC60601-1-2	Same
Safety	IEC60601-1, IEC60601-2-57, IEC60601-1-11, IEC62471	IEC60601-1, IEC60601-2-57, IEC60601-1-11, IEC62471	Same
Biocompatibility	ISO10993-5, ISO10993-10	ISO 10993-1, ISO10993-5, ISO10993-10	Same

Comparison in Detail(s):

Note 1:

Although the “Power Source” and “Power flux” are different from the predicate devices, they all complied with the IEC 60601-1, IEC 60601-1-2 and IEC 62133-2 safety standards’ requirements. So, these differences will not raise any safety or effectiveness issues.

Note 2:

Although the “Treatment Area” is different from the predicate devices, the values are very similar. So, these differences will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
- IEC 60601-1-11 Edition 2.1 2020-07 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 Edition 1.0 2011-01 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

- IEC 62133-2 Edition 1.0 2017-02 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) Biocompatibility Test

The component of the LED Eye Mask (Models: EY-20R, A20, EY-20N) has been conformed to ISO 10993-5 and ISO 10993-10.

3) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

Usability testing was conducted on the LED Eye Mask (Models: EY-20R, A20, EY-20N), which complies with IEC 62366-1 and IEC 60601-1-6.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: January 4, 2024

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K221444.