December 22, 2021

Shenzhen Kaiyan Medical Co Ltd
Alain Dijkstra
CEO
40A Fuxin Road, Fuyong Subdistrict,
BaoAn District
Shenzhen, Guangdong 518000
China

Re: K213024
Trade/Device Name: Oren LED Perioral Light Therapy System
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: October 18, 2021
Received: October 21, 2021

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)*
K213024

Device Name
Oren LED Perioral Light Therapy System (Model: OR-01)

Indications for Use *(Describe)*
The Oren LED Perioral Light Therapy System (Model: OR-01) is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral 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.

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

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**510(k) Summary of K213024**

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

**1. Date of the summary prepared: December 22, 2021**

**2. Submitter's Information**

Company: SHENZHEN KAIYAN MEDICAL CO LTD

Establishment Registration Number: 3011644607

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Phone: 0755-82129361

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Contact Person (including title): Alain Dijkstra (CEO)

Email: alaindijkstra@kaiyanmedical.com

**Application Correspondent:**

Contact Person: Mr. 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

**3. Subject Device Information**

Type of 510(k): Traditional

Classification Name: Light Based Over The Counter Wrinkle Reduction

Trade Name: Oren LED Perioral Light Therapy System

Model Name: OR-01

Review Panel: General & Plastic Surgery

Product Code: OHS

Regulation Number: 878.4810

Regulation Class: II

**4. Predicate Device Information**

Sponsor: LED Technologies, Inc.

Trade Name: reVive Perioral LED Light Therapy System

Classification Name: Light Based Over-The-Counter Wrinkle Reduction device

510(K) Number: K172662

Review Panel: General & Plastic Surgery

Product Code: OHS, ILY

Regulation Number: 878.4810

Regulation Class: II

**5. Device Description**

The Oren LED Perioral Light Therapy System (Model: OR-01) is an over-the counter light emitting diode (LED) device that emits energy for use in dermatology for treatment fine lines and wrinkles, and increase in circulation within the perioral region. The device contains four types of LEDs: 605nm amber, 630nm red, 660nm red, and 880nm infrared.

The Oren LED Perioral Light Therapy System components include the main device, Charging base, power cord, adapter. There are two buttons on the top edge of the main unit, Power button and Shutdown button. This device Only has one treatment modes.

The Oren LED Perioral Light Therapy System is applied directly to the skin to ensure consistent administration of light during each treatment. The device is sold as Over the Counter (OTC).

**6. Intended Use / Indications for Use**

The Oren LED Perioral Light Therapy System (Model: OR-01) is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral region.

**7. Comparison to predicate device and conclusion**

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

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Company | SHENZHEN KAIYAN MEDICAL CO LTD | LED Technologies, Inc. | -- |
| Trade Name | Oren LED Perioral Light Therapy System | reVive Perioral LED Light Therapy System | -- |
| Classification Name | Light Based Over The Counter Wrinkle Reduction | Light Based Over-The-Counter Wrinkle Reduction device | Same |
| 510(k) Number | K213024 | K172662 | -- |
| Product Code | OHS | OHS, ILY | Same |
| Intended Use / Indications for Use | The Oren LED Perioral Light Therapy System (Model: OR-01) is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral region. | The reVive® Perioral LED Light Therapy system is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral region. | Same |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Design | Portable equipment | Hand-held device | Similar Note 1 |
| Components | - Main device<br>- Mouthpiece<br>- Charging base<br>- Storage bag<br>- Power cord<br>- Adapter | - LED module<br>- USB charging cord<br>- Storage bag | Similar Note 3 |
| Type of use | Over-The-Counter Use | Over-The-Counter Use | Same |
| Treatment Distance | Applied directly to the skin | Applied directly to the skin | Same |
| Treatment Sites | Perioral region | Perioral region | Same |
| Change in energy (the addition of battery) | Yes | Yes | Same |
| Power Supply | 3.7V lithium battery | 3.7V lithium battery | Same |
| Time Range | 3 minutes per treatment | 3 minutes per treatment | Same |
| Wavelengths | 605nm, 630nm, 660nm, 880nm | 605nm, 630nm, 660nm, 880nm | Same |
| Number of LEDs | Total 38 LEDs<br>605nm: 10<br>660nm: 10<br>630nm: 12<br>880nm: 6 | Total 56 LEDs<br>605nm: 14<br>660nm: 14<br>630nm: 14<br>880nm: 14 | Similar Note 2 |
| Energy Level | 67.7±10% mW/cm² | 67.7mW/cm² | Same |
| Treatment Area | 24 cm² | 24 cm² | Same |
| Irradiance source | LED | LED | Same |
| Visible light LEDs | Yes | Yes | Same |
| Safety | ANSI AAMI ES60601-1 | IEC 60601-1 | Same |
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | Same |
| Biocompatibility | ISO 10993-5<br>ISO 10993-10 | ISO 10993-5<br>ISO 10993-10 | Same |
| Type/Class | OTC | OTC | Same |

**Comparison in Detail(s):**

**Note 1:**

Although the “Design” of subject device is a little different from the predicate device, they are all compliance with requirements of ANSI AAMI ES/ IEC 60601-1 and IEC 60601-1-11. So, the differences between the subject device and predicate device will not raise any safety or effectiveness issue.

**Note 2:**

Although the “Number of LEDs” of subject device is a little different from the predicate device, they are all compliance with safety standards’ requirements and they also have the same value in energy level. So, the differences between the subject device and predicate device will not raise any safety or effectiveness issue.

**Note 3:**

Although the “Components” of the subject device are a little different from the predicate device, they are both have the same output wavelengths, energy level, treatment area, and others Treatment parameters, etc. And both are all in compliance with safety standards’ requirements. So, the differences between the subject device ad predicate device will not raise any safety or effectiveness issues.

## 8. Test Summary

The Oren LED Perioral Light Therapy System (Model: OR-01) has been evaluated the safety and performance by lab bench testing as following:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11 (Edition2.0):2015-01, 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 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- 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 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62133-2 Edition1.0 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
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

## 9. Final Conclusion：

The subject device is a safe, as effective, and perform as well or better than the legally marketed predicated device K172662.