October 7, 2022

Light Tree Ventures Europe B.V.
Alain Dijkstra
Manager
Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Hague,
Netherlands

Re: K222205
Trade/Device Name: Cold Sore Device (Model: QPZ-01)
Regulation Number: 21 CFR 878.4860
Regulation Name: Light Based Energy Source Device For Topical Application
Regulatory Class: Class II
Product Code: OKJ
Dated: July 25, 2022
Received: July 25, 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,

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)*
K222205

Device Name
Cold Sore Device (Model: QPZ-01)

Indications for Use *(Describe)*
The Cold Sore Device is indicated for shortening the time to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization.

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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K222205

510(k) Summary of K222205

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

Sponsor Name: Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Contact Person (including title): Alain Dijkstra (Manager)
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E-mail: regulation@kaiyanmedical.com

Factory:

Company Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building 3, No.40, Fuxin street, Huaide Community, Fuyong Town,Baoan District, Shenzhen, Guangdong, 518103, China

Application Correspondent:

Contact Person: Alain Dijkstra
Sponsor Name: Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

2. Subject Device Information

Classification Name: Light based energy source device for topical application
Trade Name: Cold Sore Device (Model: QPZ-01)
Model Name: QPZ-01
Common Name: Light Based Treatment For Cold Sores Herpes Simplex Virus-1
Review Panel: General & Plastic Surgery
Product Code: OKJ
Regulation Number: 21 CFR 878.4860
Regulatory Class: II

3. Predicate Device Information

Sponsor: VIRULITE LLC
Trade Name: ViruLite Cold Sore Machine (ViruLite)
Classification Name: Light based energy source device for topical application
510(K) Number: DEN090012/K083767
Review Panel: General & Plastic Surgery
Product Code: OKJ
Regulation Number: 21 CFR 878.4860
Regulation Class: II

4. Device Description

The Cold Sore Device is a solid state opto-electronic device that emits a controlled quantity of 1072nm +/- 12nm peak wavelength near infrared light for a period of approximately 3 minutes. The maximum peak light intensity across the treatment surface is 20mW/cm^2. The light output and duration are monitored by a microprocessor. The tip of the device that contacts the patient is made out of Acrylonitrile Butadiene Styrene (ABS) + PC.

Treatment with the device is commenced at the first symptoms of a cold sore 3 times a day with 4 hours in between each treatment for 2 consecutive days. The treatment area is approximately 3 cm^2. There are 2 light emitting diodes (LEDs) in the treatment area. The light within the device is activated by opening the cover of the device and automatically shut down after the preprogrammed treatment time (3 minutes). The device is designed for external, limited duration skin contact in an environment free from fluids and is provided non-sterile. The LEDs do not come in direct contact with the patient based upon the design of the device. The device is for OTC use and single patient use as described in the patient and box labeling.

5. Intended Use / Indications for Use

The Cold Sore Device is indicated for shortening the time to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization.

6. Test Summary

6.1 Non-Clinical Tests Performed

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:

- AAMI/ANSI ES60601-1 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 light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
- 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 62471 Photobiological safety of lamps and lamp systems.
- 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.
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

6.2 Discussion of Clinical Tests Performed

The intended use and technical parameters of the subject device are highly consistent with the predicate device (DEN090012/K083767), and important parameters such as output wavelength, energy density, treatment time, etc. are all consistent with the predicate device (DEN090012/K083767). At the same time,

the safety of the equipment has also been tested by safety regulations, EMC and performance. So there is no clinical test on our device.

6.3 Software Validation and Verification Testing
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 of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

6.4 Human Factors/Usability
According to "Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff", the researchers conducted simulated usability tests, including self-selection, device usability, and label comprehension.
At first, the subjects will make self-selection according to the contents of the outer packaging to determine whether the subjects can make a correct self-selection, and the researchers will make judgments about the selection of the subjects. Subjects who are identified as inappropriate equipment in self-selection will be withdrawn from the study. The results showed that all 45 subjects could make self-selection correctly, and 3 subjects were not suitable for the device and withdrew from the study.
Next, the 42 subjects will undergo a usability study. The researchers will simulate the user's home environment and have subjects simulate the operation of the device. The investigator will record the operation of the subject to determine whether the using instructions provided on the user manual are understood by the subject. The results showed that all 42 subjects could perform the device usability operation correctly.
Final, the subjects will answer a series of questions related to label comprehension. Investigators will record and analyze responses to these questions to determine whether the information and instructions provided on the label were understood by the subjects. The results showed that all 42 subjects could correctly understand the information and instructions provided on the label.
After analyzing, usability test results (participating subjects could correctly perform self-selection, usability manipulation, and understanding of label content) showed that the self-selection, device usability, and label understanding of Cold Sore Devices were acceptable for patients of.

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	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	VIRULITE LLC	--
Trade Name	Cold Sore Device (Model: QPZ-01)	ViruLite Cold Sore Machine (ViruLite)	--
Classification Name	Light based energy source device for topical application	Light based energy source device for topical application	--
510(k) Number	K222205	DEN090012/K083767	--
Product Code	OKJ	OKJ	Same
Intended Use / Indications for Use	The Cold Sore Device is indicated for shortening the time to healing	The ViruLite Cold Sore Machine is indicated for shortening the time	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
	of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization.	to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization.	
Wavelengths	1072nm +/- 12nm	1072nm +/- 12nm	Same
Energy Source	LED	LED	Same
Treatment Schedule	3X/day, 4 hours between treatments, for 2 consecutive day	3X/day, 4 hours between treatments, for 2 consecutive day	Same
Auto-off feature (after 3 min treatment)	Yes	Yes	Same
Treatment time	3-minute treatment cycle	3-minute treatment cycle	Same
Treatment area	3 cm^2	7 cm^2	Different, note 1
Energy density (mw/cm^2)	20 mw/cm^2	20 mw/cm^2	Same
Power supply	Adapter: Input: 100-240Va.c., 50/60Hz, 0.35A Output: 5.0Vd.c., 1.0A Lithium battery, 3.7V, 350mAh	alkaline 9V battery	Different, note 2
Location for Use	OTC	OTC	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62471	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Note 1: Although the “Treatment area” is different from the predicate devices, the treatment area is determined by the size of the treatment window, the energy density across the treatment area is the same as that of the predicate device, so the it does not affect the effectiveness of the treatment. And they all complied with the IEC 62471 and IEC 60601-2-57 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

Note 2: Although the “Power supply” is different from the predicate devices, they all complied with the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57, IEC 62471 and IEC 62133-2 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

Final Conclusion:
The subject device is the same or similar to the legally marketed predicate device DEN090012/K083767.

8. Date of the summary prepared: September 23, 2022