September 5, 2024

Shenzhen Nuon Medical Equipment Co., Ltd
Alain Dijkstra
Regulatory Affairs Engineer
1F-3F, No.27-2, Xintang Rd, Xintian Comm, Fuhai Str,
Baoan Dist
Shenzhen, Guangdong 518000
China

Re: K241155
Trade/Device Name: Cold Sore Device (QPZ-03)
Regulation Number: 21 CFR 878.4860
Regulation Name: Light Based Energy Source Device For Topical Application
Regulatory Class: Class II
Product Code: OKJ
Dated: April 7, 2024
Received: April 25, 2024

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.

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.09.05 19:19:05 -04'00'

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)*

K241155

Device Name

Cold Sore Device (QPZ-03)

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.

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

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510(k) Summary

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: Shenzhen Nuon Medical Equipment Co., Ltd
Address:1st Floor-3rd Floor, No. 27-2, Xintang Road, Xintian Community, Fuhai Street, Baoan District, Shenzhen, Guangdong, China
Contact Person (including title): Alain Dijkstra (CEO)
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E-mail: alaindijkstra@nuonmedical.com

Application Correspondent:

Contact Person: Alain Dijkstra
Sponsor Name: Shenzhen Nuon Medical Equipment Co., Ltd
Address: 1st Floor-3rd Floor, No. 27-2, Xintang Road, Xintian Community, Fuhai Street, Baoan District, Shenzhen, Guangdong, China
Tel: +86 755 82129361
Fax: +86 755 25024651
Email: Annahe@nuonmedical.com

2. Subject Device Information

Classification Name: Light based energy source device for topical application
Trade Name: Cold Sore Device (Model: QPZ-03)
Model Name: QPZ-03
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: Light Tree Ventures Europe B.V.
Trade Name: Cold Sore Device
Model Name: QPZ-01
510(K) Number: K222205
Review Panel: General & Plastic Surgery
Product Code: OKJ
Regulation Number: 21 CFR 878.4860
Classification Name: Light based energy source device for topical application
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 pre-programmed 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:

- ANSI/AAMI ES60601-1: 2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. / IEC 60601-1:2005+AMD1:2012+AMD2:2020 Edition 3.2
- IEC 60601-1-11: 2015+AMD1:2020 Edition 2.1 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: 2023 Edition 2.0 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: 2014+AMD1:2020 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471: 2006 First edition Photobiological safety of lamps and lamp systems.
- IEC 62133-2: 2017+AMD1:2021 Edition1.0 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: 2010+AMD1:2013+AMD2:2020 Edition 3.2 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1: 2015+AMD1:2020 Edition 1.1 Medical devices - Part 1: Application of usability engineering to medical devices

6.2 Biocompatibility Test

- ISO 10993-1: 2018 Fifth edition Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.
- ISO 10993-5:2009 Third edition Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

6.3 Discussion of Clinical Tests Performed

The intended use and technical parameters of the subject device are highly consistent with the predicate device (K222205), and important parameters such as output wavelength, energy density, treatment time, etc. are all consistent with the predicate device (K222205). 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.

6.4 Software Validation and Verification Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's 2023 Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

The software documentation level was considered to be basic level, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

6.5 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 made self-selection according to the contents of the outer packaging to determine whether the subjects can make a correct self-selection, and the researchers made judgments about the selection of the subjects. Subjects who were identified as inappropriate equipment in self-selection was 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 underwent a usability study. The researchers simulated the user's home environment and had subjects simulate the operation of the device. The investigator recorded 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 answered a series of questions related to label comprehension. Investigators recorded and analyzed 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, the participating subjects could correctly perform self-selection, usability manipulation, and understand labeling content.

7. Comparison to predicate device and conclusion

Compare to the 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 Nuon Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	--
Trade Name	Cold Sore Device (Model: QPZ-03)	Cold Sore Device (Model: QPZ-01)	--
Classification Name	Light based energy source device for topical application	Light based energy source device for topical application	--
510(k) Number	TBD	K222205	--
Product Code	OKJ	OKJ	Same
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.	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.	Same
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 days	Same
Auto-off feature (after 3 min treatment)	Yes	Yes	Same
Treatment time	3-minute treatment cycle	3-minute treatment cycle	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
Treatment area	3 cm^2	3 cm^2	Same
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	Adapter: Input: 100-240Va.c., 50/60Hz, 0.35A Output: 5.0Vd.c., 1.0A Lithium battery, 3.7V, 350mAh	Same
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 IEC 60601-2-57 IEC 62133-2	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Conclusion:
The proposed device uses technology that is similar to the predicate device. The technology and design do not raise new types of questions regarding safety and effectiveness for the proposed indications for use and the performance testing supports that the device can be used safely and effectively for the proposed indications for use. The proposed device is considered to be substantially equivalent to the predicate device K222205.

8. Date of the summary prepared: September 5, 2024
Version: V5.0