November 8, 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: K241342
Trade/Device Name: Hair Growth Comb (SZ-23,SZ-23A)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 26, 2024
Received: September 26, 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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.11.08 13:45:57 -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)*

K241342

Device Name

Hair Growth Comb (SZ-23,SZ-23A)

Indications for Use *(Describe)*

The Hair Growth Comb (Model: SZ-23 ,SZ-23A,) is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

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

510(k) number: K241342

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 Nuon Medical Equipment Co., Ltd

Establishment Registration Number: 3030541658

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)

Tel: +86-755-82129361

Fax: +86-755-25024651

E-mail: alaindijkstra@nuonmedical.com

### 2. Subject Device Information

Trade Name: Hair Growth Comb

Model:SZ-23, SZ-23A

Classification Name: Laser, Comb, Hair (OAP)

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

### 3. Predicate Device Information

#### 3.1 Predicate Device 1 (K230579)

Sponsor: Light Tree Ventures Europe B.V.

Trade Name: Aduro Comb

Classification Name: Laser, Comb, Hair

510(k) Number: K230579

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

#### 3.2 Predicate Device (K211038)

Sponsor: Biophotas Inc

Trade Name: Biophotas Celluma RESTORE

Classification Name: Laser, Comb, Hair

510(k) Number: K211038

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

**3.3 Predicate Device 3 (K222477)**

Sponsor: Dongguan Lescolton Medical Equipment Co., Ltd
Trade Name: Hair Growth Device
Classification Name: Laser, Comb, Hair
510(k) Number: K222477
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

**4. Device Description**

The Hair Growth Comb is (Model: SZ-23, SZ-23A) a comb-shaped device that emits led light with the intention to promote hair growth. The device provides distributed led to the scalp at 650nm (±10nm) while the comb teeth simultaneously part the user's hair to ensure the light reaches the user's scalp. The device is designed as a handheld product, and it consists of the main unit, the charging dock and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device has only one key for switching on and off the device and it will automatically shut down after a 10-minute treatment is completed.

**5. Intended Use / Indications for Use**

The Hair Growth Comb (Model: SZ-23, SZ-23A) is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

**6. Comparison to Predicate Device**

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

| Elements of Comparison | Subject Device | Predicate Device 1 | Predicate Device 2 | Reference Device | Remark |
|---|---|---|---|---|---|
| Company | Shenzhen Nuon Medical Equipment Co., Ltd | Light Tree Ventures Europe B.V. | Biophotas Inc | Dongguan Lescolton Medical Equipment Co., Ltd | -- |
| Trade Name | Hair Growth Comb | Aduro Comb (Model: SZ-22A) | Biophotas Celluma RESTORE | Hair Growth Device | -- |
| Classification Name | Laser, Comb, Hair (OAP) | Laser, Comb, Hair (OAP) | Laser, Comb, Hair (OAP) | Laser, Comb, Hair (OAP) | -- |
| 510(k) Number | Applying | K230579 | K211038 | K222477 | -- |
| Product Code | OAP | OAP | OAP | OAP | SE |
| Intended Use / | The hair growth | The Aduro Comb | The BioPhotas | The Hair Growth | SE |

| Elements of Comparison | Subject Device | Predicate Device 1 | Predicate Device 2 | Reference Device | Remark |
|---|---|---|---|---|---|
| Indications for Use | Comb (Model: SZ-23, SZ-23A) is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I – IV. | (Model: SZ-22A) is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV. | Celluma RESTORE is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV. | Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV. All users should have Fitzpatrick Skin Types I to IV. | |
| Wavelengths | 650±10nm | 650±10nm | 640nm (±25nm) | 650-660nm | SE |
| Treatment time | Each Treatment: 30 min<br>Total Treatment: every other day, for 16 weeks | Each Treatment: 30 min<br>Total Treatment: every other day, for 16 weeks | Each Treatment:30 min Total Treatment: every other day, for 16 weeks | LS-D620：20 minutes each time for 16 weeks<br>LS-D630：12 minutes each time for 16 weeks | SE |
| Treatment area | 31.5 $cm^2$ | 31.5 $cm^2$ | 475 $cm^2$ | No publicly available | SE |
| Energy density ($mw/cm^2$) | SZ-23: 2.77 $mw/cm^2$<br>SZ-23A: 5.54$mw/cm^2$ | 2.77 $mw/cm^2$ | 2.77 $mw/cm^2$ | 40$mW/cm^2$ | SE<br>NOTE 1 |

| Elements of Comparison | Subject Device | Predicate Device 1 | Predicate Device 2 | Reference Device | Remark |
|---|---|---|---|---|---|
| Treatment Dose(J/cm$^2$) | SZ-23: 4.98 J/ cm$^2$<br>SZ-23A: 9.96 J/ cm2 | 4.98 J/ cm$^2$ | 4.98 J/ cm$^2$ | No publicly available | SE<br>NOTE 2 |
| Energy Source | Light emitting diodes | Light emitting diodes | Light emitting diodes | Low-level laser diodes | SE |
| Number of LEDs | SZ-23: 22 LEDs<br>SZ-23A: 11 LEDs | 22 LEDs | No publicly available | LS-D620 Laser diodes: 80<br>LS-D630 Laser diodes: 162 | SE |
| Power supply | Input: DC 5 V, 2 A<br>Battery: DC 3.7 V, 600 mAh, 2.22 Wh | Input: 100-240V~, 50/60Hz, 0.35Amax<br>Output:5V, 2A<br>Battery: DC 3.7 V, 600 mAh, 2.22 Wh | 110-120V | No publicly available | SE |
| Location for Use | OTC | OTC | OTC | OTC | SE |
| Safety and EMC | IEC 60601-1<br>IEC 60601-1-11<br>IEC 62471<br>IEC 60601-2-57<br>IEC 60601-1-2<br>IEC 62133-2 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 62471<br>IEC 60601-2-57<br>IEC 60601-1-2<br>IEC 62133-2 | IEC 60601-1<br>IEC 60601-1-2 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 60601-2-57<br>IEC 60601-1-2<br>IEC 60825-1 | SE |
| Biocompatibility | All patient contacting materials comply with ISO 10993-5, ISO 10993-10 | All patient contacting materials comply with ISO 10993-5, ISO 10993-10 | All patient contacting materials comply with ISO 10993-5, ISO 10993-10 | All patient contacting materials comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 | SE |

**7. Test Summary**

**7.1 Non-Clinical Tests Performed**

**1) Electrical safety, and electromagnetic compatibility**

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 req uirements for basic safety and essential performance. / IEC 60601-1:2005+AMD1:2012+AMD2:2020 E dition 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

**2) Biocompatibility**

There is one patient directly contracting materials in the subject device as the following list.

| Component of Device Requiring | Material of Component | Body Contact Category (ISO 10993-1) | Contact Duration (ISO 10993-1) |
|---|---|---|---|
| Shell | PC+ABS | Surface-skin | Less than 24 hours |

The Nature of body contact is surface, skin contact. And the contact duration is less than 24 hours. According to “Table A.1 - Initial evaluation tests for consideration” in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or intracutaneous reactivity (ISO 10993-10)

Hair Growth Comb (Model: SA-23, SA-23A) is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization). So, ISO 10993-5 and ISO 10993-10 test reports have been provided.

**3) Software verification and validation testing**

Software verification and validation testing were conducted and documentation was provided as recommended by the IEC 62304 and FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff" The level of the documentation of the software for was considered as a "basic" level, since a failure or a latent design flaw could directly lead to a minor Injury to the patient or operator.

**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.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 K230579, K211038 and K222477.

**Summary Prepared Date:2024-11-7**

Version: V5.0