September 13, 2024

Revian, Inc.
Tammy Carrea
VP Quality, Regulatory, and Clinical Affairs
615 Davis Drive
Suite 800
Morrisville, North Carolina 27560

Re: K242441
Trade/Device Name: Revian Lyte (10011)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 15, 2024
Received: August 16, 2024

Dear Tammy Carrea:

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: 2024.09.13 11:13:04 -04'00'

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)*

K242441

Device Name

Revian Lyte (10011)

Indications for Use *(Describe)*

The Revian Lyte device is indicated to treat Androgenetic Alopecia and to 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.

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

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**Revian Lyte 510(k) Summary** K242441

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

Date: September 12, 2024

## 1. Submitter Information:

| | |
|---|---|
| Submitted By: | Revian Inc.<br>615 Davis Drive<br>Suite 800<br>Morrisville, NC 27560 |
| Contact: | Tammy B. Carrea<br>VP Quality, Regulatory, and Clinical Affairs<br>Regulatory2@revian.com |

## 2. Device Information:

| | |
|---|---|
| Trade or Proprietary Name: | Revian Lyte |
| Model Number: | 10011 |
| Common or Usual Name: | Low Level Light Therapy (LLLT), Non-heating, For Promotion of Hair Growth |
| Regulation Name: | Infrared Lamp |
| Regulation: | 21 CFR Part 890.5500 |
| Classification: | Class II |
| Classification Panel: | General and Plastic Surgery |
| Product Code: | OAP |

# Revian Lyte 510(k) Summary

## 3. Predicate and Reference Device Information:

| **Predicate:** | **Sponsor:** | **Device Name:** | **510(k) Number:** |
|---|---|---|---|
| | Revian, Inc. | Revian Red | K173729 |
| **Reference Device:** | **Sponsor:** | **Device Name:** | **510(k) Number:** |
| | Slinph Technologies Co., Ltd | iHelmet (LTD88Lite, LTD36Air, LTD160Pro) | K190467 |

## 4. Purpose of the Special 510(k):

Two modifications were made to the Revian Lyte device: (1) the number and position of the treatment LEDs were modified and, (2) the user interface was modified to provide notifications via firmware/hardware only versus a mobile application and firmware/hardware in the Revian Red device.

## 5. Indications For Use:

Revian Lyte is intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa to 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 to IV.

## 6. Device Description:

The Revian Lyte device is a model (10011) within the Revian Red (10001) family of devices.

Revian Lyte is an over the counter (OTC) home-use, non-invasive, hands-free device indicated to treat androgenetic alopecia in both men and women and promote hair growth using Modulated Light Therapy (MLT) and a 10-minute daily treatment. The Revian Lyte cap is designed to treat the scalp and temple areas. The device is a non-sterile, single user, multi-use therapy device.

Revian Lyte is a system comprised of a wearable soft textile cap and protective inner liner together which encase driver electronics, a rechargeable battery, and an integrated light emitting diode (LED) array on a flexible Printed Circuit Board (PCB). The protective inner liner, a plastic lenticular lens, covers the treatment LED array and electronics and is in

direct contact with the patient's scalp. The lenticular lens disperses LED light over the treatment area. The Revian Lyte device emits non-coherent visible red light at two target peak wavelengths (620nm and 660nm).

When the Lyte cap is placed onto the head, a capacitive touch sensor (proximity sensor) embedded in the flexible printed circuit board senses the presence of the scalp and turns on the cap. Removable and adjustable foam headliners ensure that the cap fits snugly on the scalp and ensure that the proximity sensor is in close contact with the scalp. A series of blinking indicator LEDs and audible tones provide information to the user such as the status of battery charge, treatment status, etc. At the end of treatment, a series of 3 audible beeps signal that the treatment has finished and the device automatically shuts off. Lyte is controlled via embedded firmware.

The battery is recharged between uses using an AC power adapter and a USB charging cable.

The Revian Lyte includes:

(1) A treatment cap with integrated electronics,

(2) Accessory Kit containing the USB Charging Cable with AC Power Adaptor and set of Adjustable Headliners,

(3) Clear Charging Base used to rest the Cap when not in use and to rest the Cap to charge between treatments and,

(4) Instructions for Use (IFU).

## 7. Substantial Equivalence to Predicate Device:

The Revian Lyte model has the same intended use, indications for use, principle of operation and technological characteristics as the predicate device. The two devices are essentially the same in terms of materials and design. There are two technological differences between the Revian Red model and Revian Lyte, (1) the number and position of the treatment LEDs and, (2) the user interface for device notifications.

# Revian Lyte 510(k) Summary

| Characteristic | Predicate Device | Reference Device | Proposed Device | Proposed Device Verdict |
|---|---|---|---|---|
| **Device** | Revian Red | iHelmet Hair Growth System (models LTD88Lite, LTD36Air, LTD160Pro) | Revian Lyte | Revian Lyte |
| **510(k) #** | K173729 | K190467 | | |
| **Company** | Revian, Inc. (previously known as PhotonMD, Inc.) | Slinph Technologies Co., Ltd | Revian, Inc. (previously known as PhotonMD, Inc.) | Same as Revian Red |
| **Product Code** | OAP | OAP | OAP | Same as Revian Red |
| **Rx/OTC** | OTC | OTC | OTC | Same as Revian Red |
| **Use Environment** | Home Use | Home Use | Home Use | Same as Revian Red |
| **Intended Use/ Indications for Use** | Treat androgenetic alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to 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 to IV. | iHelmet Hair Growth System (LTD88Lite, LTD36Air, LTD160Pro) is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I-II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa to V and for both, Fitzpatrick Classification of Skin Phototypes I to IV. | Treat androgenetic alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to 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 to IV. | Same as Revian Red |
| **Wearable Mounting** | Textile Cap, Hands Free | Hard shell cap | Textile Cap, Hands Free | Same as Revian Red |
| **Wave-Length(s)** | 620 +/- 10 nm to 660 +/- 10 nm | 650 +/- 10 nm | 620 +/- 10 nm to 660 +/- 10 nm | Same as Revian Red |
| **Visible Light Source** | Light Emitting Diodes | Laser Diodes | Light Emitting Diodes | Same as Revian Red |
| **Number of Lights** | 119 LEDs<br>59 Orange at 620 +/10 nm<br>60 Red at 660 +/-10 nm | 88, 36, 160 respectively<br>(LTD88Lite, LTD36Air, LTD160Pro) | 102 Total LEDs<br>52 Orange at 620 +/- 10 nm<br>50 Red at 660 +/-10 nm | Similar to Revian Red<br>102 Total LEDs<br>52 Orange at 620 +/- 10 nm<br>50 Red at 660 +/-10 nm |
| **LED Location** | Over scalp, temple, and nape of head (donor area). | Over scalp and temple. | Over scalp and temple. | Same as iHelmet |

# Revian Lyte 510(k) Summary

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|---|---|---|---|---|
| **Battery** | Lithium Polymer | Rechargeable Battery Pack | Lithium Polymer | Same as Revian Red |
| **Treatment Time/ Treatment Length** | Once per day for 10 mins | Each Treatment: 30 min<br>Total Treatment: every other day, for 16 weeks | Once per day for 10 mins | Same as Revian Red |
| **Digital Mobile Application** | Yes | iHelmet also does not utilize a mobile app for device notifications. | The LYTE user interface does not utilize a mobile application. All device notifications are via indicator LEDs and audible tones. | Same as iHelmet<br><br>The LYTE user interface does not utilize a mobile application. All device notifications are via indicator LEDs and audible tones. |
| **Treatment Initiation** | Treatment is started after the cap is placed onto head and sensed by a proximity sensor and the user initiates a treatment via the mobile app. | Treatment is started after the cap is placed onto the head and the start button is pushed. | Treatment is auto-started after the cap is placed onto the head and sensed by a proximity sensor. | Similar to Revian Red<br><br>Treatment is auto-started after the cap is placed onto the head and sensed by a proximity sensor. |
| **Device/System Uses** | Reusable, single patient (a 2nd user can be added through the app). | Unknown | Reusable, single patient (a 2nd user cannot be added). | Similar to Revian Red<br><br>Reusable, single patient (a 2nd user cannot be added). |
| **Frequency of Use** | Limit of one treatment per 24 hours via mobile application and instructions for use. | Instructions for Use specify frequency of use. No mobile app to restrict frequency. | Instructions for Use specify frequency of use. No mobile app to restrict frequency. | Same as iHelmet |
| **Other Design Characteristics** | Cap pauses therapy if subject's head moves outside zone of radiation. | Cap pauses therapy if removed. | Lyte cap pauses if removed during treatment. | Same as Revian Red and iHelmet.<br><br>Lyte cap pauses if removed during treatment. |
| | When treatment paused, and cap connected to app, cap is placed back onto head and app resumes. If treatment paused and cap not connected to app, treatment resumes automatically when cap placed back on head. | When cap placed back onto head, treatment resumes automatically. | When cap placed back onto head, treatment resumes automatically. | Same as Revian Red and iHelmet.<br><br>When cap placed back onto head, treatment resumes automatically. |

# Revian Lyte 510(k) Summary

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|---|---|---|---|---|
| | After completion of treatment, unit powers down and beeps. | Unit powers down and beeps after treatment. | Unit powers down after treatment and beeps. | Same as Revian Red and iHelmet.<br><br>Unit powers down after treatment and beeps. |
| | Limits daily treatment to 10 mins, (limits treatments to one per day/24 hours via the app). | No means to limit treatments to one per 24 hours.<br>Use limits stated in IFU. | No means to limit treatments to one per 24 hours.<br>Use limits stated in IFU. | Same as iHelmet<br><br>No means to limit treatments to one per 24 hours.<br>Use limits stated in IFU. |
| | Provides treatment reminders and messages via mobile app controller. | No mobile app to provide treatment notifications or mobile user interface. | No mobile app to provide treatment notifications or mobile user interface. | Same as iHelmet<br><br>No mobile app to provide treatment notifications or mobile user interface. |

## 8. Comparison of Technological Characteristics with Predicate and Reference Device:

There are two technological differences between the Revian Lyte cap and the Revian Red cap, (1) the number and position of the treatment LEDs and, (2) the user interface for device notifications using firmware/hardware versus a mobile application with firmware/hardware. The Revian Red device utilizes 119 treatment LEDs positioned over the scalp, temple, and nape of the head (donor area). The Revian Lyte utilizes 102 LEDs positioned over the scalp and temple. Similar devices on the market also utilize varying quantities of laser diodes or LEDs and in varying positions. Specifically, similar to the iHelmet reference device, the Revian Lyte model has a different number of LEDs than Red and has LEDs in the scalp and temple area but not in the nape of the head (donor area).

The second difference between the Revian Red and Revian Lyte is the utilization of a mobile app and bluetooth module to provide a user interface for device notifications. In conjunction with firmware/hardware, the Revian Red device uses a mobile application and bluetooth data transfer to control various functions of the device and to provide a user interface for device notifications. However, for the Revian Lyte, rather than using a mobile app, the Lyte relies solely on hardware and firmware to provide the user interface for device notifications.

Risks associated with these modifications were identified and no risks were considered as unacceptable. The risks have been mitigated and the effectiveness of the mitigations has been verified and validated through testing. These differences do not raise new or different issues of safety and effectiveness from the predicate device.

## 9. Non-Clinical Test Summary:

Safety:

The Revian Lyte was evaluated and bench tested for optical safety and passed. Agency review found Lyte equivalent to Revian Red per IEC 62471.

Lyte was agency evaluated by an NRTL lab to IEC 60601-2-57 and is compliant.

Additionally, the Lyte device was agency tested and evaluated for compliance to other relevant IEC medical device safety standards including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-1-11 and is compliant.

Performance:

The Revian Lyte was tested for optical performance and electrical characteristics and passed all requirements.

Firmware Verification/Validation:

Removal of the mobile application resulted in modifications to the control board and firmware. These modifications were verified/validated via firmware validation.

Cybersecurity:

The subject device has no any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.

Usability:

Removal of the mobile application resulted in modifications to the instructions for use and the user interface. These modifications were verified/validated via usability/human factors testing.

Biocompatibility:

There were no changes to the tissue contacting materials. No biocompatibility testing was performed.

Summary:

Any technological differences and associated risks between the Revian Red model and the Revian Lyte model have been mitigated via verification and validation testing. Thus, the Revian Lyte device does not introduce any new issues of safety or effectiveness compared to Revian Red or other similar LED hair growth devices currently marketed.

## 10. Clinical Test Summary:

No clinical information is included in this submission.

## 11. Conclusions:

The conclusion drawn from the test data is that the Revian Lyte device is as safe and effective as the predicate device, has the same indications for use and principle of operation as the predicate device, performs similarly to the predicate device, and does not raise any new or different issues of safety and effectiveness.