September 17, 2024

Telebrands Corporation
Shepard Bentley
Regulatory Affairs Consultant
One Telebrands Plaza
Fairfield, New Jersey 07004

Re: K240689
Trade/Device Name: Robin's Egg
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 16, 2024
Received: August 16, 2024

Dear Shepard Bentley:

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: 2024.09.17 15:39:24 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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.

510(k) Number *(if known)*
K240689

Device Name
Robin's Egg

Indications for Use *(Describe)*
The Robin's Egg 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-I to I-4, II-I, 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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Robin's Egg

510(k) Summary # K240689

This summary of 510(k) safety and effectiveness information in being submitted in accordance with the requirements of SMDA and 21 CFR §890.5500.

1.1 Submitter Information:

Sponsor: Telebrands Corporation
One Telebrands Plaza,
Fairfield, NJ 07004

Contact Person: Shepard G. Bentley, RAC
Regulatory Affairs Consultant
Phone: (949) 374 – 9187
Email: sbentley@bentleybiomed.com

***Preparation Date*:** 16 September 2024

1.2 Subject Device Information

Trade/Proprietary Name:	Robin's Egg
Regulations Name:	Infrared Lamp per 21 CFR §890.5500
Product Code:	OAP (laser, comb, hair)
Regulation Number:	21 CFR §890.5500
Regulatory Class:	Class 2

1.3 Predicate Device Information

Predicate Device: REVIAN RED K173729 PhotonMD, Inc.

1.4 Device Description

The Telebrands' Robin's Egg is a non-invasive, helmet-style photobiomodulation device indicated to treat androgenetic alopecia in both men and women. It is operated using a single button at the front of the helmet to promote hair growth using Modulated Light Therapy (MLT) for a recommended 10-minute daily treatment. The Robin's Egg is a system comprised of a wearable soft textile Cap using driver electronics, a rechargeable battery, and integrated light emitting diode (LED) flexible printed circuit board containing 126 LEDs, as compared to 119 within the predicate device REVIAN RED. The Robin's Egg is designed as an over-the-counter (OTC) home-based device to treat the entire scalp area of the user

and is controlled by means of a single button and illuminated control display at the front of the helmet. Emitting red light energy within the 625 – 660 nm at 2.376 mW/cm^2 for a treatment time of 10 minutes, the Robin's Egg provides a well-established photobiomodulation effect upon the scalp to stimulate hair growth.

1.5 Indications for Use

The Robin's Egg 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.

1.6 Performance Test Summary

No clinical trial data for the Robin's Egg was submitted for this 510(k). Non-clinical performance testing to demonstrate substantial equivalence to the predicate device included evaluation to current versions of IEC 60601-1 (Edition 3.2 2020-08) and 60601-1-2:2014 to confirm the device's electrical safety and electromagnetic compatibility, and conformance with ANSI/AAMI 60601-1-11:2015, IEC 60601-2-57 (Edition 1.0), and IEC 62471 (Edition 1.0). Biocompatibility testing of the Cap per ISO 10993-1:2018 confirmed no effects of the applied parts with particular attention to cytotoxicity, skin irritation or skin sensitization.

In addition, performance verification and validation testing demonstrate that the Robin's Egg meets user needs and design inputs and met requirements for its intended use and spectral and irradiance parameters of the subject are equivalent to the similar parameters of the predicate device.

Studies Related to Human Factors Evaluation

Human factors evaluation of the Robin's Egg was performed following the current versions of ANSI/AAMI/IEC 62366-1:2015 and 60601-1-6 (Edition 3.2 2020-07) standards. The study protocol was designed to evaluate representative users of the device under expected conditions during simulated and actual use of the device. The Human Factors Engineering and Usability Engineering process involved several methodologies, including observational user research, formative and summative user testing.

1.7 Comparison to Predicate Device

Robin's Egg has similar technological characteristics as the REVIAN RED (K173729), including wavelength, light energy delivery method, timers and intended use.

Table 1 – Summary of Predicate Device Comparison

510(k) #	K240689	K173729

Device	Robin's Egg	REVIAN RED
Company	Telebrands Corp.	PhotonMD, Inc.
Product Code	OAP	OAP
Rx/OTC	OTC	OTC
Intended Use/Indications for Use	The Robin's Egg 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.	The Robin's Egg 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.
Wearable Mounting	Textile Cap	Textile Cap
Wavelengths	625 – 660 nm	620 – 660 nm
Visible Light source	126 Red LEDs	119 Red LEDs
Battery	Lithium Polymer	Lithium Polymer
Treatment Time	Every day 10 minutes	Every day 10 minutes
Restrictions of Daily Irradiance	Yes, daily limit for treatments	Yes, daily limit for treatments

1.8 Conclusion

This notification contains all information required by 21 CFR 807.87. Performance testing including electrical, electromagnetic compatibility, biocompatibility, software, and human factors demonstrates Robin's Egg meets the requirements for its intended use and does not raise any new types of safety or effectiveness questions when compared to the predicate device.

End 510(k) Summary