February 28, 2018

PhotonMD, Inc
Mr. William Knape
Senior Director, Regulatory Quality and Clinical Affairs
627 Davis Drive, Suite 400
Morrisville, North Carolina 27560

Re: K173729
Trade/Device Name: Revian Red
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 4, 2017
Received: December 6, 2017

Dear Mr. Knape:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173729

Device Name
REVIAN RED

Indications for Use *(Describe)*

REVIAN RED 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1 510(K) Summary

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

1.1 Submitter Information:

Sponsor: PhotonMD, Inc.
627 Davis Drive, Suite 400
Morrisville, NC 27560

Contact Person: William A. Knape
Senior Director of Regulatory, Quality and Clinical Affairs
Phone: (919) 757-2033
Email: bknape@photonmd.com

Submission Date: December 4, 2017

1.2 Subject Device Information

Trade/Proprietary Name	*REVIAN RED (Model 101)*
Common/Usual Name:	Lamp for Promotion of Hair Growth
Regulation Name:	Infrared Lamp per 21 CFR 890.5500
Review Panel:	General & Plastic Surgery
Product Code:	OAP (laser, comb, hair)
Regulation Number:	21 CFR 890.5500
Regulatory Class:	Class 2

1.3 Predicate Device Information

Predicate Devices:

Device	510(k) Number	Manufacturer
iHelmet Hair Growth System	K162782	Slinph Technologies
HairMD	K152019	Trophy Skin
HairMax LaserComb 82	K142573	Lexington International
LH80 PRO	K122950	Theradome

1.4 Device Description

REVIAN RED is a non-invasive, hands-free device indicated to treat androgenetic alopecia in both men and women. It is operated via a mobile application to promote hair growth using Modulated Light Therapy (MLT) for a recommended 10-minute daily treatment. *REVIAN RED* 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. *REVIAN RED* is designed as an over-the-counter (OTC) home-based device to treat

the entire scalp area of the user and is controlled via a wireless Bluetooth connection to a mobile application operating on a wireless device.

1.5 Indications for Use

The *REVIAN RED* 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 *REVIAN RED* System was submitted for this 510(k). Non-clinical performance testing to demonstrate substantial equivalence to the predicate device included evaluation to IEC 60601-1 and 60601-1-2 to confirm the device's electrical safety and electromagnetic compatibility and conformance with ANSI/AAMI HA60601-1-11:2015, IEC 60601-2-57 (Edition 1.0), and IEC 62471 (Edition 1.0). Biocompatibility testing of the Cap per ISO 10993-1 confirmed no effects of the applied parts were noted for cytotoxicity, skin irritation or skin sensitization. Performance verification and validation testing demonstrates *REVIAN RED* meets user needs and design inputs and met requirements for its intended use.

Studies Related to Human Factors Evaluation

Human factors evaluation of *REVIAN RED* was tested following ANSI/AAMI/IEC 62366-1 and 60601-1-6 standards. The study protocol was designed to evaluate representative users of the device under expected use 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 Devices

REVIAN RED has similar technological characteristics as the iHelmet Hair Growth System (K162782) including wavelength, light energy delivery method, mobile app interface with interactive audible timers and intended use. *REVIAN RED* is also similar technologically to the other helmet designed devices; with HairMD (K152019) and LH80 PRO (K122959) having fewer diodes (51 laser diodes/LEDS and 80 laser diodes, respectively) and longer treatment regimens of 20 minutes.

Table 1 – Summary of Predicate Devices Compared to *REVIAN RED*

510(k) #	K173729	K162782	K152019	K142573	K122950
Device	*REVIAN RED*	iHelmet Hair Growth System (LTD200S)	HairMD	HairMax LaserComb 82 (HMLC 82)	LH80 PRO
Company	PhotonMD, Inc.	Slinph Technologies	Trophy Skin	Lexington International	Theradome
Product Code	OAP	OAP	OAP	OAP	OAP
Rx/OTC	OTC	OTC	OTC	OTC	OTC
Intended Use/ Indications for Use	Treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classification 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	Promote hair growth in females with Androgenetic Alopecia who have Ludwig-Savin Classification of I-II, in males with Androgenetic Alopecia who have Norwood Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I - IV.	Promote hair growth in females with Androgenetic Alopecia who have Ludwig-Savin Classification of I-II, in males with Androgenetic Alopecia who have Norwood Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I - IV.	Treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classification IIa to V patterns of hair loss and treat Androgenetic Alopecia and, promote hair growth in females who have Ludwig (Savin) scale I-4, II-1, II-2 or frontal, both with Fitzpatrick skin types I to IV.	Treat Androgenetic Alopecia, to promote hair growth in females with female pattern hair loss (FPHL) on the Ludwig and Savin Hair Loss Scale I-II, Fitzpatrick Skin-Types I to IV.
Wearable Mounting	Textile Cap	Helmet	Helmet	Head Band	Helmet
Wave-Length(s)	620 - 660 nm	650 nm ±10nm	650 nm	655 nm ±10nm	678 nm
Visible Light source	119 Red LEDs	200 Red Laser Diodes	21 Red Laser Diodes and 30 Red LEDs	82 Red Laser Diodes	80 Red Laser Diodes
Battery	Lithium Polymer	Lithium Polymer	Powered by 120V Wall Plug	Lithium Polymer	Lithium Polymer

Table 1 – Summary of Predicate Devices Compared to *REVIAN RED* (cont'd)

510(k) #	K173729	K162782	K152019	K142573	K122950
Treatment Time	Every day 10 mins	Every other day 20-35 mins	Every other day 20 mins	3 times / week 90 seconds	2 times / week 20 mins
Digital Mobile Controller	Yes	Yes	No	No	No
Restrictions on Daily Irradiance	Yes, daily limit for treatments	No	No	No	No
Other Design Characteristics	Cap pauses therapy if subject's head moves outside zone of radiation; after completion of treatment, unit powers down, limits daily treatment to 10 mins, and provides treatment reminders and messages via mobile app controller	Helmet pauses therapy if subject's head moves outside zone of radiation; after completion of time, unit powers down and audible beep.	Helmet pauses therapy if subject's head moves outside zone of radiation; after completion of time, unit powers down and audible beep.	Vibrate so user can move to the next section, 3 sections @ 30 seconds each, proximity sensor to shut off lasers if not in contact, 7.5 cm scalp section, automatic turn off	Helmet pauses therapy if subject's head moves outside zone of radiation; after completion of time, unit powers down and audible beep.

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 *REVIAN RED* 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.