August 10, 2018

PJM Worldwide, LLC d/b/a Phoenix Medical Technology, LLC
% Ronald Berglund
Member/Manager
Grace Consulting, LLC
6615 Lake Shore Drive, Suite 806
Minneapolis, Minnesota 55423

Re: K181253
Trade/Device Name: Bosley Revitalizer 272 Laser Cap, Bosley Revitalizer 164 Laser Cup
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: May 8, 2018
Received: May 30, 2018

Dear Ronald Berglund:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181253

Device Name
BOSLEY Revitalizer 272 Laser Cap; BOSLEY Revitalizer 164 Laser Cap

Indications for Use *(Describe)*

The BOSLEY Revitalizer 272 and 164 Laser Caps are indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-3, or frontal; both with Fitzpatrick Skin Types I to 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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Premarket Submission Applicant Name/510k Holder: Phoenix Medical Technology, LLC

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Official Correspondent: Ronald Berglund, GRACE Consulting, LLC
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Date of Original Submission: May 22, 2018

Device Name(s) and Classification

Product Name(s) and Models: BOSLEY Revitalizer 272 Laser Cap
BOSLEY Revitalizer 164 Laser Cap

Product Code: OAP
Regulation Number: 21 CFR 890.5500
Panel: General and Plastic Surgery
Class: II (performance standards)

Predicate Devices:

Illuniflow Laser Cap (K162071)—Cleared for OTC use;

Grivamax Hair Growth System (K171895)-Cleared for OTC use;

Theradome LH80 PRO (K122950)—Cleared for OTC use;

Capillus 272 Pro (K143199) — original clearance for use in females; K160285 — adds treatments for males to the indications for use of all Capillus models)

Reference Devices:

iGrow-II Hair Growth System (K122248; K140931, additional indication for use in females; K141567, original clearance for use in males)

HairMax LaserComb 82 (now sold as the HairMax LaserBand) (K142573, hands-free version of the HairMax LaserComb for use in males and females)

Substantial Equivalence:

The BOSLEY Revitalizer 272 Laser Cap and BOSLEY Revitalizer164 Laser Cap are substantially equivalent to the referenced predicate devices based on indications for use, manufacturing materials, physical specifications, and performance specifications. The BOSLEY Revitalizer 272 and 164 Laser Caps raise no safety or efficacy concerns when compared to the predicate devices.

Description of the Device:

The BOSLEY Revitalizer 272 and 164 Laser Caps are low level laser therapy (LLLT) devices designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of 272 or 164 visible red light-emitting diodes at 650-nm and 5mW each. The lasers are contained inside a lightweight cap. The device is powered by an included battery pack and automatically turns off after 30 minutes.

Intended Use/Indications for Use:

The BOSLEY Revitalizer 272 and 164 Laser Caps are indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-3, or frontal; both with Fitzpatrick Skin Types I to IV.

Technological Characteristics:

The BOSLEY Revitalizer 272 and 164 Laser Caps and the predicate devices have the following similar and substantially equivalent technological characteristics:

- *Design/Operating Principle:* Both the BOSLEY Revitalizer 272 and 164 Laser Caps and the predicate devices are LLLT/photobiostimulation devices (with either 272, 202, 82 or 80 laser diodes) in cap form for the hands-free delivery of 650-nm visible red light to the scalp in order to treat androgenic alopecia and stimulate hair growth.
- *Energy Source:* The BOSLEY Revitalizer 272 and 164 Laser Caps and the predicate devices are powered by Lithium-ion battery packs. The batteries can be recharged with the provided standard AC adapters.

- *Performance:* The BOSLEY Revitalizer 272 and 164 Laser Caps and the predicate devices provide timed 30-minute LLLT treatments.

The predicate Illumiflow Laser Cap, Grivamax Hair Growth System, Capillus 272 Pro and Theradome LH80 Pro are cleared as OTC devices.

Other minor differences between the subject and predicate devices are summarized below:

- The BOSLEY Revitalizer 272 and 164 Laser Caps do not contain a 'safety interlock' which automatically pauses therapy if the subject's head is in a less-than-optimal position.
- The BOSLEY Revitalizer 272 and 164 Laser Caps can detect whether or not the device is on the user's head.

No new questions of safety and effectiveness have been raised as a result of these differences. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.

Biocompatibility:

Biocompatibility tests of the patient-contacting materials were tested by Mid-Link Technology Testing Co., Ltd., Tianjin, China in accordance with FDA Good Laboratory Practice Regulations (21 CFR Part 58) and International Organization for Standardization 10993-10, Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization and 10993-5:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, ISO 14971:2007 - Medical devices—Application of risk management to medical devices, FDA General Program Memorandum #G95-1, and FDA's Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.(Part 5: Tests for In Vitro Cytotoxicity). Biocompatibility tests were selected appropriate for the duration and type of contact to the device design of the BOSLEY Revitalizer 272 and 164 Laser Caps.

Cytotoxicity tests performed on the BOSLEY Revitalizer 272 and 164 Laser Caps demonstrated that the material used in the manufacturing of the caps is non-cytotoxic. The caps were considered by the testing facility to have met the requirements of ISO 10993-1:2009, ISO 14971:2007, and FDA General Program Memorandum #G95-1, for surface devices with limited contact (<24 hours) with the skin and was considered safe for use. Skin sensitization tests performed on the BOSLEY Revitalizer 272 and 164 Laser Caps further demonstrated that the material used in the manufacturing of the caps were not considered a sensitizer in the tests performed.

Non-clinical Performance Testing:

Performance tests were conducted in support of the design verification of the BOSLEY Revitalizer 272 and 164 Laser Caps to confirm compliance to design specifications; all functions were verified to operate as designed, the BOSLEY Revitalizer 272 and 164 Laser Caps met all acceptance criteria in the performance testing.

Testing to IEC 60825-1 certifies the laser system to classification 3R, which is the same as the predicate devices. The BOSLEY Revitalizer 272 and 164 Laser Caps were also tested and complies with Electrical Safety and EMC testing, which include the requirements of IEC 60601-1:2012 3rd Edition "Medical Electrical Equipment Part 1— General Requirements for Safety" IEC 60601-1-2 "Medical Electrical Equipment Part 1-2, General Requirements for Safety — Collateral Standard Electromagnetic Compatibility Requirements and Tests IEC and 60601-1-11 Home healthcare medical equipment. The charger conforms to IEC 60950 and the battery to IEC 62133.

Over-the-Counter/Usability Testing:

A single study was conducted in February 2018 in 30 female participants and 30 male participants to judge self-selection, comprehension of labeling and instructions, and usability of the Bosley Revitalizer Laser Cap. Each participant was provided with a Survey and Consent Form and a document entitled “Am I a Candidate for Usage of the Bosley Laser Cap?” These documents described the purpose of the study, the basic procedure steps, a consent form, permission to use their photos and non-disclosure terms.

Each participant was provided the proposed retail package for the Bosley Revitalizer Laser Cap, instructions for use, and the survey form containing 13 questions. Each participant was given as much time as he or she needed to read and understand the packaging information (an understanding of indications, contraindications, warnings and precautions), and assess whether they were within any contraindicated group. Assistance was available from the interviewer, but none of the study participants asked for assistance. The subjects were required to answer all questions. The interviewer verified that the participant completed the questionnaire in his or her presence. One male was excluded from the study as he wore a hair system (toupee) and thus his answers could not be verified. The total male population in the analysis is 29. A series of global photos using superior (male and female) and vertex (male only) were taken by the interviewer.

The survey forms and photos were securely stored electronically is a single folder for each participant. After completion of the data acquisition an independent reviewer verified completeness of the survey forms and the acceptable quality of the photos. Then, a licensed physician skilled in hair loss and skin clinical studies rated the participants pictures for hair loss and skin type.

An independent blinded statistician was provided a chart of hair loss rating and skin type rating, gender, and participant identifier. Consistent with the requirements cited in the comprehension and usability studies for the other laser cap devices granted over-the-counter clearance by the FDA, an 80% success rate was required.

All participants in the Bosley study accurately categorized their skin type as suitable candidates for treatment or not a suitable candidate when compared with physician ratings (i.e. 100%). Zero females and three males incorrectly identified themselves as treatment candidates for treatment based on hair loss. This means 100% of women and 90% of men correctly identified their candidacy for treatment or incorrectly judged themselves unsuitable for treatment based on hair loss self-rating. Overall, 95% percent of participants judged themselves correctly on hair loss.

Based on the data submitted and reviewed in the Statistical Analysis of the Comprehension and Usability Study of Revitalizer Laser Cap, Phoenix Technology LLC believes the Bosley Revitalizer Laser Cap for males and females should be granted the OTC intended use as requested.

Conclusion:

Based on the non-clinical verification performance testing and as described above, it can be concluded that the BOSLEY Revitalizer 272 and 164 Laser Caps are substantially equivalent to the predicate Illumiflow, Theradome, Grivamax and Capillus Pro 272 Laser Caps (K162071, K122950, K171895 and K143199)
with respect to intended use, principles of operation and technological characteristics. No new questions of safety and effectiveness have been raised as a result of the minor differences between the devices. All non-clinical verification performance testing was done using the BOSLEY Revitalizer 272 Laser Cap. The only difference between the BOSLEY Revitalizer 272 and 164 Laser Caps is the number of laser diodes contained in the product. Phoenix Technology LLC believes the results of the non-clinical performance testing based on the use of 272 laser diodes would have been virtually identical had the 164 laser diode model been tested instead. In addition, the predicate Theradome LH80 PRO (K122950)—also cleared for OTC use—utilized only 80 laser diodes and was found to be substantially equivalent to the other predicates cited. Based on the data submitted and reviewed in the Statistical Analysis of the Comprehension and Usability Study of Revitalizer Laser Cap, Phoenix Technology LLC believes the Bosley Revitalizer Laser Cap for males and females should also be granted the OTC intended use as requested.