PJM Worldwide, LLC d/b/a Phoenix Medical Technology, LLC
℅ Ronald Berglund
Member/Manager
Grace Consulting, LLC
6615 Lake Shore Drive, Ste 605
Minneapolis, Minnesota 55423

Re: K192585
Trade/Device Name: Bosley Revitalizer 96 Laser Cap, Bosley Revitalizer 96 XL Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 27, 2019
Received: January 3, 2020

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/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 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 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,

Jessica Mavadia-Shukla
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192585

Device Name
Bosley Revitalizer 96 Laser Cap

Indications for Use *(Describe)*
The Bosley Revitalizer 96 Laser Cap is indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of Ila 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-2, 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.

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K192585

Special 510(k) Summary

Date: December 27, 2019

Submitter's Contact Information:

Name: Ronald E. Berglund, GRACE Consulting, LLC

Address: 6615 Lake Shore Drive #605, Richfield, MN 55423

Establishment Registration #: 3008855505
Owner/Operator #: 10059366

Telephone: (952)220-3014
Facsimile: (952)888-8282

Name of Device and Name / Address of Sponsor:

Trade Name: Bosley Revitalizer 96 Laser Cap

Common or Usual Name: Lamp, non-heating, for promotion of hair growth

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: PJM Worldwide, LLC d/b/a Phoenix Medical Technology, LLC
1499 Northwest 79th Av., Miami, FL 33126

Telephone: (305)477-2515

Predicate Devices:

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

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

Capillus 272, 202 and 82 LLLT Devices (K143199; K150578; K151516; K153618; K163170 and K160285)

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)

Intended Use / Indications for Use:

The Bosley Revitalizer 96 Laser Cap is indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of Ila 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-2, or frontal; both with Fitzpatrick Skin Types I to IV.

Technological Characteristics

The Bosley Revitalizer 96 Laser Cap incorporates the same technology as the Bosley Revitalizer 272 and 164 Laser Caps in every way **except** the following:

The Bosley Revitalizer 96 Laser Cap has fewer diodes – 96 compared to 272 and 164 for the Bosley Revitalizer 272 and 164 Laser Caps

The Bosley Revitalizer 272 Laser Cap consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer cap and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Bosley Revitalizer 164 Laser Cap consists of 164 red, visible light, diode lasers operating at 650 nanometers, configured within an outer cap and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Bosley Revitalizer 96 Laser Cap consists of 96 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. Just as with the Bosley Revitalizer 272 and 164 Laser Caps, the 96 Laser Cap system can detect whether or not the device is in the correct position on the user's head and will automatically pause therapy if it is not. The device will resume therapy when the correct head position is re-established. The system is powered by rechargeable Lithium-ion battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant with recognized, international standards.

Design Control Activities:

The Bosley Revitalizer 96 Laser Cap design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes include assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and risk management file and summary are available for review. Based on the Bosley Revitalizer 272 and 164 Laser Caps, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers (≤ 5mw); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Bosley Revitalizer Laser Caps that are currently cleared under device code OAP and utilize much fewer than 272 lasers.

Instructions for use with the Bosley Revitalizer 96 Laser Cap do not change from the instructions provided with the Bosley Revitalizer 272 and 164 Laser Caps. Indications for use and the dose schedule remain exactly the same as for the Bosley Revitalizer 272 and 164 Laser Caps and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day. The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

a) **General:** The Beijing Toplaser Technology Co., Ltd. Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30. The main design activities included the following: 1.) identification of product technical solutions; 2.) risk analysis; and 3.) product validation.

b) **Design and development planning**: During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from the previous models revealed no significant changes or risks identified for the new model Bosley Revitalizer 96 Laser Cap. Vigilance activities for the Bosley Revitalizer 96 Laser Cap indicated that there were no significant problems identified (no adverse events reported).

c) **Design input**: Design requirements for the Bosley Revitalizer 272 and 164 Laser Caps are transferred to the Bosley Revitalizer 96 Laser Cap and an input/output matrix was completed for the project.

d) **Design output**: Design requirements for the Bosley Revitalizer 272 and 164 Laser Caps are transferred to the Bosley Revitalizer 96 Laser Cap. Design outputs are verified per performance tests.

e) **Design review**: Appropriate design reviews were conducted. Due to the minimal modifications made (i.e., only the reduced number of laser diodes), a technical evaluation and a verification of inputs and outputs (physical values) were completed.

f) **Design verification**: All verification activities to assess the impact of the modification (reduction of number of laser diodes) were completed. It was determined that the laser

diode output remained the same, but the total dosage is reduced due to the lower number of laser diodes used with the new model. Since the cap is intended to be used indefinitely (if treatment is stopped the results are lost), the reduced number of laser diodes will likely affect only the time required for users to experience the same results as achieved with the Bosley Revitalizer 272 and 164 Laser Caps. The Bosley Revitalizer 96 Laser Cap is offered as a lower-cost alternative to the original models.

g) **Design validation**: Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The modestly lower efficacy is accepted by users, with the understanding that treatment is intended to be continued indefinitely.

h) **Design Transfer**: The Bosley Revitalizer Laser Cap family of products are manufactured on-site in the facility of the manufacturer in Beijing, China. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes**: The design of all models follows the manufacturer's established design control, change control, and document control procedures.

j) **Design history**: The design history file for the Bosley Revitalizer 96 Laser Cap is available for review.

Performance Data:

All verification and validation activities were performed by designated individuals.

The product design change (reduction of number of laser diodes) was carried out in accordance with the control requirements of design and development activities as detailed in ISO13485 and CFR820, and records of all activities have been maintained.

The Bosley Revitalizer 96 Laser Cap is a new model modified on the basis of the Bosley Revitalizer 272 and 164 Laser Caps. With the new 96 model the number of laser diodes has been reduced from either 272 or 164 to 96. The parameters of the laser such as wavelength, and output power remain unchanged. The control method, software and usage method also remain the same as with the Bosley Revitalizer 272 and 164 Laser Caps. The risk analysis method utilized was failure modes and effects analysis (FMEA)-- a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. FMEA incorporates each of the following risk analysis components:

- **"Failure modes"** (the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual);
- **"Effects analysis"** (refers to studying the consequences of those failures). Failures are prioritized according to how serious their consequences are, how frequently they occur, and how easily they can be detected. The purpose of FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority failures. Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is initially used during design to prevent failures, but after production has begun it is used for control, before and during ongoing operation of the process.

Based on the risk analysis report (Documents No.: FRZ/TZ-YA-12) produced for the Bosley Revitalizer 272 and 164 Laser Caps, the risks caused by the laser diode reduction of this change have been analyzed one by one. The conclusion is that there is no new unacceptable risk due to the reduced number of laser diodes.

New product samples of the 96-laser diode model have been tested to meet the requirement and the test methods utilized were identical to the test methods utilized for the Bosley Revitalizer 272 and 164 Laser Caps (Test report number: FRZ/JL-T-028). Due to changes in product specifications, the identification label has been modified and new models have been added to the operation manual.

Due to the reduction of the laser diodes, the corresponding product BOM has also been modified. There is, however, no change in the manufacturing process flow. The results of the verification and validation activities (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications. All functions of the modified product have been verified to operate as designed, and all acceptance criteria were met by the new device. The Bosley Revitalizer 96 Laser Cap conforms to the following recognized standards: IEC-60601-1, IEC-60601-11, IEC-60601-2-22 (2007/Third Ed.), and IEC60825-1 (Ed. 3). These IEC standards are recognized and accepted standards by the FDA. The guidance document for these standards is found in the Federal register, July 26, 2001 (volume 66, Number 144). This report validates for the Bosley Revitalizer 96 Laser Cap the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959. The performance data -- available for review-- demonstrates that the Bosley Revitalizer 96 Laser Cap has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the Bosley Revitalizer 272 and 164 Laser Caps cleared under K181253. Total "dose" – delivered energy over time – (J/cm^2) is reduced due to the reduced number of laser diodes. However, since the cap is intended to be used indefinitely (if treatment is stopped, results are lost), it is believed that the reduced number of laser diodes will

only affect the time required to witness the same result as achieved with the Bosley Revitalizer 272 and 164 Laser Caps. Just as for the Bosley Revitalizer 272 and 164 Laser Caps (K181253) and reference devices, there have been no reported adverse events for these products.

Substantial Equivalence

The Bosley Revitalizer 96 Laser Cap is the same technology used by Bosley Revitalizer 272 and 164 Laser Caps (K181253) and other reference devices; specifically, iGrow-II Hair Growth System (K122248 and K140931). The Bosley Revitalizer 96 Laser Cap is as safe and (commensurate to number of diodes) effective as the Bosley Revitalizer 272 and 164 Laser Caps, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Predicate Comparison Table

Bosley Revitalizer 96 Laser Cap	Bosley Revitalizer 272/164 Laser Caps	Illumiflow Laser Cap	Grivamax Hair Growth System	Capillus272, Capillus202, Capillus82	Ihelmet Hair Growth System	Theradome
K192585	K181253	K162071	K171895	K163170, K153618, K160285	K162782	K122950
LLLT Device Type	LLLT Device Type	LLLT Device Type	LLLT Device Type	LLLT Device Type	LLLT Device Type	LLLT Device Type
OTC Use	OTC Use	OTC Use	OTC Use	OTC Use	OTC Use	OTC Use
Intended Use - Androgenic Alopecia+promote hair growth	Intended Use - Androgenic Alopecia+promote hair growth	Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia+promote hair growth	Intended Use - Androgenic Alopecia+promote hair growth	Intended Use - Androgenic Alopecia in adult females
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650 nm	650 nm	650 nm	650 nm	650 nm	650 nm	678 nm
Marketing clearance for males and females	Marketing clearance for males and females	Marketing clearance for males and females	Marketing clearance for males and females	Marketing clearance for males and females	Marketing clearance for males and females	Marketing clearance for females
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free
96 Laser Diodes (5 mW ea.)	272 and 164 Laser Diodes (5 mW ea.)	272 Laser Diodes (5 mW ea.)	272 Laser Diodes (5 mW ea.)	272, 202 and 82 Laser Diodes	200 Laser Diodes	80 laser diodes
Dimensions: Bosley 96: 180 mmX180 mm X 95 mm (L X W X H) Bosley 96XL:	Dimensions: Bosley 272: 180 mm X 180 mm X 95 mm (L X W X H) Bosley 164:				Dimensions: 266 mm X 196 mm X 135 mm (L X W X H)	

200 mm X 200 mm X 112 mm (L X W X H)	180 mm X 180 mm X 95 mm (L X W X H)					
OAP Classification	OAP Classification	OAP Classification	OAP Classification	OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp	Classification Name - Infrared Lamp	Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name -Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Photo-types - I- IV	Fitzpatrick Skin Photo-types - I- IV	Fitzpatrick Skin Photo-types - I- IV	Fitzpatrick Skin Photo-types - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Photo-types - I- IV	Fitzpatrick Skin Phototypes - I- IV
Ludwig-Savin I-1 to I-4, II-1, II-2 or frontal (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-1 to I-4, II-1, II-2 or frontal (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I1 to I-4, II-1, II-2, or frontal (females) + Norwood Hamilton IIa-V (males)	Ludwig-Savin I1 to I-4, II-1, II-2, or frontal (females) + Norwood Hamilton IIa-V (males)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo		
Treatment- 16 weeks, every other day (indefinite)	Treatment- 16 weeks, every other day (indefinite)	Treatment- 16 weeks, every other day (30 min. per session)	Treatment- 16 weeks, every other day (30 min. per session)	Treatment- 17 weeks, every other day (indefinite)	Treatment- 16 weeks, every other day (20 – 35 min. per session)	Treatment—20 minutes, twice per week (non-consecutive days)
Treatment Area: Bosley 96: 218 cm2 Bosley 96XL: 240cm2 Mathematically Max. Derived	Treatment Area: Bosley272: 509 cm2 Bosley164: 328 cm2 Mathematically Max. Derived			Treatment Area: Capillus272: 495.37 cm2 Capillus202: 449.51 cm2 Capillus82: 194.42 cm2 Mathematically Max. Derived	Treatment Area: 424.93 cm2 Mathematically Max. Derived	
Irradiance (power per area): Bosley 96: 2.2 mW/ cm2 Bosley 96XL: 2.0 mW/ cm2 Mathematically Max. Derived	Irradiance (power per area): Bosley272: 2.67mW/cm2 Bosley164: 2.5 mW/cm2 Mathematically Max. Derived			Irradiance (power per area): Capillus272: 2.7454 mW/ cm2 Capillus202: 2.2469 mW/cm2 Capillus82: 2.1088 mW/cm2 Mathematically Max. Derived	Irradiance (power per area): 2.3533 mW/ cm2 Mathematically Max. Derived	
Energy Fluence: Bosley 96: 3.96 J/cm2 Bosley 96XL: 3.6 J/cm2 Mathematically Max. Derived	Energy Fluence: Bosley272: 4.8 J/cm2 Bosley 164: 4.5 J/cm2 Mathematically Max. Derived			Energy Fluence: Capillus272: 4.9417 J/cm2 Capillus202: 4.044 J/cm2 Capillus82: 3.792 J/cm2 Mathematically Max. Derived	Energy Fluence: 4.9420 J/cm2 Mathematically Max. Derived	
Device Class II	Device Class II	Device Class II	Device Class II	Device Class II	Device Class II	Device Class II

The submitter believes that with the exception of the number of laser diodes and the configuration of the optical elements, the Bosley Revitalizer 96 Laser Cap is the same device in form, function, safety, and efficacy as the previous versions and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. The submitter believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Bosley Revitalizer 96 Laser Cap satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are raised due to the minor differences between these devices.