PLM Worldwide, LLC d/b/a Phoenix Medical Technology, LLC
℅ Ronald Berglund
Official Correspondent
Grace Consulting, LLC
8609 Lyndale Ave S
Suite 205
Bloomington, Minnesota 55420

Re: K240456
Trade/Device Name: Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 14, 2024
Received: February 15, 2024

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 (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.

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: 2024.05.22 14:17:36 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240456

Device Name
Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap

Indications for Use *(Describe)*

The Bosley Booster 128 Laser Cap, Bosley Booster 162 Laser Cap, and Bosley Booster 288 Laser Cap 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-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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K 240456 Special 510(k) Summary for Bosley Booster Family of Laser Caps

Date: May 20, 2024

Submitter's Contact Information:

Name: Ronald E. Berglund, GRACE Consulting, LLC

Address: 8609 Lyndale Av. S., Ste 205, Bloomington, MN 55420

Establishment Registration #: 3008855505
Owner/Operator #: 10059366

Telephone: (952)955-9755
Facsimile: (952)888-8282

Name of Device and Name / Address of Sponsor:

Trade Name: Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 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:

Bosley Revitalizer 96 Laser Cap (K192585)- Cleared for OTC use;
Bosley Revitalizer 272 and 164 Laser Caps (K181253)- Cleared for OTC use;

Reference Devices:

Dongguan Lescolton Hair Growth Device (K210169)- Cleared for OTC use;
Nooance LED and Laser Helmet (K231321)- Cleared for OTC use;
iRestore Laser Cap (K183417)- Cleared for OTC use.

K 240456 Special 510(k) Summary for Bosley Booster Family of Laser Caps

Intended Use / Indications for Use:

The Bosley Booster 128 Laser Cap, Bosley Booster 162 Laser Cap, and Bosley Booster 288 Laser Cap 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-2, or frontal; both with Fitzpatrick Skin Types I to IV.

Technological Characteristics

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

The Bosley Booster 128 has 51 red, visible light laser diodes (LDs) and 77 light-emitting diodes (LEDs). The Bosley Booster 162 has 65 red, visible light laser diodes (LDs) and 97 light-emitting diodes (LEDs). The Bosley Booster 288 has 115 red, visible light laser diodes (LDs) and 173 light-emitting diodes (LEDs). The LDs and LEDs utilized all have a wavelength of 650 nanometers and a power output of 5 mW each, and are configured within an outer cap and protective inner liner, configured for portable use with rechargeable battery and adapter.

The predicate Bosley Revitalizer 164 Laser Cap utilizes 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 272 Laser Cap utilizes 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 96 Laser Cap utilizes 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, 164 and 96 Laser Caps, the Bosley Booster Family of laser Caps 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 devices 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 Booster Family of Laser Caps 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 effects different numbers of diode lasers and/or LEDs would have on the end product, both for safety and for efficacy. All residual risks have been found to be acceptable. Based on the Bosley Revitalizer 272, 164 and 96 Laser Caps, the verification and validation activities remain the same (e.g. output of each laser diode or LED, 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.

Safety ratings remained the same; there was no change to the output of the individual laser diodes or LEDs (≤ 5mw); however, the "dose" (total delivered energy/cm2) may vary slightly due to number of laser diodes and/or LEDs utilized. This may affect efficacy; this observation is made based on the performance of other devices similar to the Bosley Revitalizer and Booster Family of Laser Caps that are currently cleared under device code OAP and utilize a wide variety of numbers of laser diodes and/or LEDs.

Instructions for use with the Bosley Booster Family of Laser Caps do not change materially from the instructions provided with the Bosley Revitalizer 272, 164 and 96 Laser Caps. Indications for use and the dose schedule remain similar to those utilized for the Bosley Revitalizer 272, 164 and 96 Laser Caps and as for other devices in the same category (product code OAP); which is for a treatment duration of 25 minutes each day. The output of the laser diodes and LEDs was verified to remain the same (each diode and LED) as for the predicate models. 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 design changes for the Bosley Booster Family of Laser Caps. The proposed design change was minimal and affected only the number of laser diodes and LEDs utilized in each PCB array. The power packs remain exactly the same. Review of the risk assessment from the previous models revealed no significant changes or risks identified for the new Bosley Booster Family of Laser Caps. Vigilance activities for the Bosley Booster Family of Laser Caps indicated that there were no significant problems identified (no adverse events reported).
c) **Design input**: Design requirements for the Bosley Revitalizer 272, 164 Laser Caps have been transferred to the Bosley Booster Family of Laser Caps and an input/output matrix was completed for the project.
d) **Design output**: Design requirements for the Bosley Revitalizer 272, 164 and 96 Laser Caps have also been transferred to the Bosley Booster Family of Laser Caps. 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 variations in the number of laser diodes and LEDs

utilized), 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 modifications (i.e., the variations in the number of laser diodes and LEDs utilized) were completed. It was determined that the total power output remained the same, but the total dosage may vary due to the variations in the number of laser diodes and LEDs utilized with the new models. Since the cap is intended to be used indefinitely (if treatment is stopped the results are lost), the variations in the numbers of laser diodes and LEDs will likely affect only the time required for users to experience the same results as achieved with the Bosley Revitalizer 272, 164 and 96 Laser Caps. The Bosley Booster Family of Laser Caps is offered as a lower-cost alternative to the earlier 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 Booster Family of Laser Caps 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 Booster Family of Laser Caps affirms that appropriate design reviews were conducted. Due to the minimal modifications made from previously-cleared models, a technical evaluation and a verification of inputs and outputs (physical values) were completed.

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 Booster Family of Laser Caps is comprised of new models modified on the basis of the Bosley Revitalizer 272, 164 and 96 Laser Caps. With the new models the number of laser diodes utilized along with LEDs varies slightly between the different models. The parameters of the laser diodes and LEDs 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,

164 and 96 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 produced for the Bosley Revitalizer 272, 164 and 96 Laser Caps, the risks caused by variations in the numbers of laser diodes and LEDs utilized in these models 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 Bosley Booster models have been tested to meet the requirements and the test methods utilized and were identical to the test methods utilized for the Bosley Revitalizer 272, 164 and 96 Laser Caps. Due to changes in product specifications, the identification labels have been modified and a new user manual has been created for the Bosley Booster Family of Laser Caps.

Due to variations in the number of laser diodes and LEDs utilized with the different models, the corresponding product bills of materials have also been modified. There is, however, no change in the manufacturing process flow. The results of the verification and validation activities demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications. All functions of the modified products have been verified to operate as designed, and all acceptance criteria were met by the new devices. The Bosley Booster Family of Laser Caps 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 Booster Family of Laser Caps 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 demonstrates that the Bosley Booster Family of Laser Caps has exactly the same diode laser and LED wavelengths, output power (per diode laser or LED), and treatment area as the Bosley Revitalizer 272, 164 and 96 Laser Caps cleared under K181253 and K192585. Total "dose" – delivered energy over time – (J/cm^2) may vary slightly due to the variations in the number of laser diodes and/or LEDs utilized in the various models. However, since the cap is intended to be used indefinitely (if treatment is stopped, results are lost), it is believed that the slight variations in the number of laser diodes and/or LEDs utilized will only affect the time required to witness the same result as achieved with the Bosley Revitalizer 272, 164 and 96 Laser Caps. Just as for the Bosley Revitalizer 272, 164 and 96 Laser Caps and predicate devices cited, there have been no reported adverse events for these products.

Device Description

The Bosley Booster Family of 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 photo-stimulation of visible, red laser diodes and LEDs at 650-nm and 5mW each. The lasers and diodes are contained inside a lightweight cap. The device is powered by an included battery pack and automatically turns off after 30 minutes. The Bosley Booster Family of Laser Caps are identical to the cleared Bosley Revitalizer 272, 164 and 96 Laser Caps with the exception of the number of included low level laser diodes (LDs) and LEDs as shown below:

1. Configuration of Models

Model	Number of LDs	Number of LEDs
Booster 128	51	77
Booster 162	65	97
Booster 288	115	173

K 240456 Special 510(k) Summary for Bosley Booster Family of Laser Caps

Substantial Equivalence

The Bosley Booster Family of Laser Caps utilize the same technology as the predicate Bosley Revitalizer 272, 164 and 96 Laser Caps (K181253 and K192585) and other predicate and reference devices cited below:

Predicate and Reference Device Comparison Table

Comparisons with Predicate Devices						
Table 1 Technical Characteristics in Comparison to Predicate Devices						
510K number	- --	K181253	K192585	K210169	K231321	K183417
Proprietary name	Bosley Booster Laser Cap Family	Bosley Revitalizer Laser Cap	Bosley Revitalizer	Hair Growth Device	Shenzhen Kaiyan Medical Equipment Co., Ltd.	iRestore Laser Cap
Model	Booster 128, 162, and 288	272/164 laser caps	96 laser caps	LS-D601	NOOANCE LED AND LASER HELMET M-120 and M-282 PRO	Professional 282
Manufacturer	Beijing Top Laser Technology Co., Ltd.	Beijing Top Laser Technology Co., Ltd.	Beijing Top Laser Technology Co., Ltd.	Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	Raymond R. Blanche
Regulation number	890.5500	890.5500	890.5500	890.5500	890.5500	890.5500
Regulation name	Infrared lamp	Infrared lamp	Infrared lamp	Infrared lamp	Infrared Lamp	Infrared Lamp
Regulation Class	Class II	Class II	Class II	Class II	Class II	Class II
Product Code	OAP	OAP	OAP	OAP	OAP	OAP
Common Name	Laser, comb, hair	Laser, comb, hair	Laser, comb, hair	Laser, comb, hair	Laser, comb, hair	Laser, comb, hair
Review Panel	General and plastic surgery	General and plastic surgery	General and plastic surgery	General and plastic surgery	General and plastic surgery	General and plastic surgery
Indications for Use	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and

					Fitzpatrick Classification of Skin Phototypes I to IV.	Fitzpatrick Classification of Skin Phototypes I to IV.
Intended User	Female and Males	Females and Males	Females and Males	Females and Males	Females and Males	Females and Males
Type of use	OTC	OTC	OTC	OTC	OTC	OTC
Mode of Operation	Low-level laser diodes and light-emitting diodes	Low-level laser diodes	Low-level laser diodes	Low-level laser diodes and light-emitting diodes	Low-level laser diodes and light-emitting diodes	Low-level laser diodes and light emitting diodes
Wavelength	650 nm	650 nm	650 nm	650 nm	650 nm	650 nm
No. of light source	128 model: 57 LDs 77 LEDs 162 model: 65 LDs 97 LEDs 288 model: 115 LDs 173 LEDs	272 and 164 laser diodes	96 laser diodes	Laser diodes: 26 LED diodes: 30	M-120: LDs: 51 LEDs: 69 M-282 PRO: LDs: 82 LEDs:200	LDs: 82 LEDs: 200
Power Output	5 mW per light	5 mW per light	5 mW per light	5 mW per light	5 mW per light	5 mW per light
Treatment duration	25 minutes every day	30 minutes every other day	16 minutes every other day	25 minutes every other day for 16 weeks		
Power supply	Power adapter	Power adapter	Power adapter	Power Adapter	Power adapter	Power adapter
Irradiance	128 model: 1.43 mw/ cm2 162 model: 1.68 mw/ cm2 288 model: 2.47 mw/ cm2	Irradiance (power per area) Bosley 272: 2.67mW/cm2 Bosley 164: 2.5 mW/cm2 Maximum mathematically derived	Irradiance (power per area): Bosley 96: 2.2mW/cm2 Bosley 96XL: 2.0 mW/ cm2 Maximum mathematically derived		M-120: Approximately 1.3 mw/cm2 M-282 PRO: Approximately 2.8 mw/cm2	N/A
Fluence	128 model: 1.72 J/cm2 162 model: 2.02 J/cm2 288 model: 2.96 J/cm2	Energy Fluence: Bosley 272: 4.8 J/cm2 Bosley 164: 4.5 J/cm2 Mathematically max derived	Energy Fluence: Bosley 96: 3.96 J/cm2 Bosley 96XL: 3.6 J/cm2 Mathematically max derived		M-120: Approximately 1.9J/cm2 M-282 PRO: Approximately 4.2 J/cm2	N/A
Distribution	Uniform	Uniform	Uniform	Uniform		
Dimensions	Bosley Booster 128, 162 and 288 models: 195 mm x 179 mm x 90 mm (L x W x H)	Dimensions: Bosley 272: 180 mm 180 mm x 95 mm (L W x H) Bosley 164: 200 mm x 200 mm x 112 mm (L x W x H)	Dimensions: Bosley 96: 180 mm x 180 mm x 95 mm (L x W x H) Bosley 96XL: 180 mm x 180 mm x 95 mm (L x W x H)			
Treatment area	370 cm2	Bosley272: 509 cm2 Bosley164: 328 cm2	Bosley 96: 218 cm2 Bosley 96XL: 240 cm2			

Conclusion

The submitter believes that with the exception of slight variations in the number of laser diodes and LEDs utilized and slight differences in the configuration of the optical elements, the Bosley Booster Family of Laser Caps are the same devices in form, function, safety, and efficacy as the previous Bosley versions and the predicate device(s) cited above. The submitter believes that the minor differences in the physical appearance, the number of laser diodes and/or LEDs utilized, 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 Booster Family of Laser Caps 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.