December 19, 2017

Super Grow Lasers
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies
2834 Hawthorn Street
San Diego, California 92104

Re: K172982
Trade/Device Name: SuperGrow 272, Ultimate 272
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 26, 2017
Received: September 27, 2017

Dear Allison Komiyama:

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)*
K172982

Device Name
SuperGrow 272 - Ultimate 272

Indications for Use *(Describe)*
The SuperGrow 272 laser hat and the Ultimate 272 are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood – Hamilton Classifications of 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; 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K172982

510(k) Summary

DATE PREPARED
September 26, 2017

MANUFACTURER AND 510(k) OWNER
Super Grow Lasers
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PROPRIETARY NAME OF SUBJECT DEVICE
SuperGrow 272 and Ultimate 272

COMMON NAME
Laser, Comb, Hair

DEVICE CLASSIFICATION
21 CFR 890.5500, Product Code OAP, Class II

PREMARKET REVIEW
ODE/DSD/ General Surgery Devices Branch One (GSDB1)
General and Plastic Surgery

INDICATIONS FOR USE
The SuperGrow 272 laser hat and the Ultimate 272 are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood – Hamilton Classifications of 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; both with Fitzpatrick Skin Types I to IV.

DEVICE DESCRIPTION

The SuperGrow 272 and the Ultimate 272 are non-invasive, low level laser therapy (LLLT) devices each containing 272 red, visible light, diode lasers. The devices are designed to deliver non-thermal energy to the hair follicles via photostimulation of the scalp. The SuperGrow 272 consists of 272 red, visible light, diode lasers operating at a 650 nanometer wavelength (maximum output power of each is 5 mW). The diodes are configured within a cap, enclosed between the outer shell and inner liner, both made of polyethylene terephthalate (PET). The Ultimate 272 is exactly the same as the SuperGrow 272 in every way except it is mounted on a stand. The same electrical design (power supply and the on/off switch) has been applied to the Ultimate 272. In the Ultimate 272, the SuperGrow 272, is inserted into a dome attached to a stand, and is intended for in-office use.

PREDICATE DEVICE IDENTIFICATION

The SuperGrow 272 and Ultimate 272 are substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K163170	Capillus272Pro, Capillus 272 OfficePro / Capillus, LLC.	✓

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the SuperGrow 272 and the Ultimate 272. The following tests were performed to demonstrate safety based on current industry standards:

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to IEC 60601-1, IEC60601-1-2 and IEC 60601-1-11

Performance and Laser Safety: The subject device was tested in compliance to IEC 60825-1.

The results of these tests indicate that the SuperGrow 272 and the Ultimate 272 are substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

SuperGrow Lasers believes that the SuperGrow 272 and the Ultimate 272 are substantially equivalent to the predicate devices based on the information summarized here:

The subject devices have similar designs and dimensions, and use similar materials as the devices cleared in K163170. The subject devices have the same intended use and similar technological characteristics (laser wavelength, amount of diodes, energy per diode, output mode) to the devices cleared in K163170. Any differences in technological characteristics (power source) do not raise different questions of safety and effectiveness. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

CONCLUSION

Based on the testing performed, including laser safety, electromagnetic compatibility, and electrical safety, it can be concluded that the subject devices do not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed SuperGrow 272 and Ultimate 272 are assessed to be substantially equivalent to the predicate devices. The devices are considered safe and effective for their intended use.