August 15, 2018

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

Re: K181308
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: May 15, 2018
Received: May 17, 2018

Dear Ms. 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. 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,

David Krause -S

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)*
K181308

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)

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."

510(k) Summary
K181308

DATE PREPARED
August 10, 2018

MANUFACTURER AND 510(k) OWNER
Super Grow Lasers
1903 Commonwealth #16,
Houston, TX 77006, U.S.A.
Telephone: +1 (713) 551-6320
Official Contact: Jeffrey Stanifer, CEO

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
Lucie Dalet, Ph.D.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 208-7888
Email: akomiyama@acknowledge-rs.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	SuperGrow 272 and Ultimate 272
Common Name:	Laser, Comb, Hair
Regulation Number:	21 CFR 890.5500
Class:	II
Product Code:	OAP
Premarket Review:	ODE/DSD/General Surgery Devices Branch One (GSDB1)
Review Panel:	General and Plastic Surgery

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K172982	SuperGrow 272 and Ultimate 272 / Super Grow Lasers	✓
K163170	Capillus272Pro, Capillus 272 OfficePro / Capillus, LLC.	

The predicate devices have not been subject to a design related recall.

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.

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

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 identical designs and dimensions, and use identical materials as the devices cleared in K172982. The subject devices have the same intended use and identical or similar technological characteristics (laser wavelength, amount of diodes, energy per diode, output mode) as the devices cleared in K172982 and K163170. The only difference between the subject devices and those cleared in K172982 is that the indications are being expanded to include over-the-counter use (similar to the indications for the devices cleared in K163170).

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 was evaluated per IEC 60601-1, IEC60601-1-2 and IEC 60601-1-11. Biocompatibility was evaluated per ISO 10993-1.

CLINICAL TESTING

The capability of the average “retail customer” to self-select and appropriately use the subject device without the counsel of a health care provider was evaluated in a usability study. The study was conducted on 40 subjects of both genders, with a wide range in age, educational background, and disease status, as a sample of the intended use population. The first part of the study evaluated the ability of the subjects to decide if they were an appropriate user based on the indications and contraindications listed on the packaging. The second part assessed the ability of the subjects to understand the instructions for use, warnings, and precautions

provided inside a standard retail package. An observer evaluated the ability of the subjects to properly use the device according to the instructions provided. To demonstrate equivalence for OTC distribution, a minimum of an 80% success rate was required. For each part of the test, all questions had to be answered correctly in order to pass. The results of each part were considered independently. With a passing rate of 80% for self-selection, 82.5% for the comprehension of the instructions, and 80% for the proper use of the device, the results of the usability testing demonstrate that the SuperGrow 272 and the Ultimate 272 are safe for over-the-counter distribution.

CONCLUSION

Based on the testing performed, including usability testing, it can be concluded that the subject devices do not raise new issues of safety or effectiveness compared to the predicate devices. The similar or identical 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 device