November 16, 2022

Xtrallux, LLC
% Freeman Anike
Principal Consultant
Rqm+
2251 San Diego Avenue
Suite B-257
San Diego, California 92110

Re: K222364
Trade/Device Name: Xtrallux Alpha (XA136R-USA), Xtrallux Super Plus (XS276R-USA/XS276L-USA), Xtrallux Turbo Pro (XP316R-USA), Xtrallux Extreme RX (XR352R-USA)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: October 20, 2022
Received: October 20, 2022

Dear Freeman Anike:

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222364

Device Name
Xtrallux Alpha (XA136R-USA); Xtrallux Super Plus (XS276R-USA/XS276L-USA);
Xtrallux Turbo Pro (XP316R-USA); Xtrallux Extreme RX (XR352R-USA)

Indications for Use *(Describe)*
The Xtrallux Alpha, Super Plus, Turbo Pro, and Extreme RX are intended to treat Androgenetic Alopecia (AGA) and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and, 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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510(k) Summary
K222364

DATE PREPARED
November 15, 2022

MANUFACTURER AND 510(k) OWNER
Xtrallux
7260 NW 58th Street
Miami, FL 33166
USA
Telephone: (888) 425-0290
Official Contact: Carlos Piña

REPRESENTATIVE/CONSULTANT
Anike Freeman, MEng, PMP
Allison C. Komiyama, PhD, RAC
RQM+
Telephone: +1 (412) 899-7422
Email: afreeman@rqmplus.com, akomiyama@rqmplus.com

DEVICE INFORMATION

Proprietary Name:	Xtrallux Alpha, Xtrallux Super Plus, Xtrallux Turbo Pro, Xtrallux Extreme RX
Common Name:	Laser, comb, hair
Regulation Number:	21 CFR 890.5500
Class:	II
Product Code:	OAP
Premarket Review:	General Surgery Devices (DHT4A)
Review Panel:	General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
The Xtrallux devices are substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K192012	CapillusX & CapillusX+ by Capillus	✓
K163170	Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352	
K180885	HairMax Laser by Lexington International, LLC	Reference

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION

The Xtrallux devices are non-invasive, low level laser therapy (LLLT) devices containing red, visible light diode lasers operating at 650 nm wavelength. The maximum power output of each diode is 5 mW. The diodes are configured within a cap, enclosed between the outer shell and inner liner. They deliver non-thermal energy to hair follicles via photostimulation of the scalp and are intended to stimulate hair growth. Xtrallux has developed four models:

- Xtrallux Alpha
- Xtrallux Super Plus
- Xtrallux Turbo Pro
- Xtrallux Extreme RX

INDICATIONS FOR USE

The Xtrallux Alpha, Super Plus, Turbo Pro, and Extreme RX are intended to treat Androgenetic Alopecia (AGA) and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and, 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

Xtrallux believes that the Xtrallux Devices are substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use and similar design as the predicate devices cleared in K192012 and K163170. The subject device also has the same technological characteristics (laser wavelength, number of laser diodes, energy per laser diode, and total output mode) as the predicate devices.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Xtrallux devices. The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility:

The subject device was evaluated for cytotoxicity, sensitization, and irritation in compliance to ISO10993-5:2009 and ISO 10993-10:2010.

Electromagnetic Compatibility and Electrical Safety:

The subject device was tested in compliance to IEC 60601-1:2005, IEC 60601-1-2:2014, IEC 60601-1-6:2010, and IEC 60601-1-11:2015

Performance and Laser Safety:
The subject device was tested in compliance to IEC 60825-1:2014.

Usability:
Xtrallux conducted a usability study to confirm consumers could appropriately self-select and correctly operate the Xtrallux devices.

The results of these tests indicate that the Xtrallux devices are substantially equivalent to the predicate devices.

CONCLUSION
Based on the non-clinical testing performed it can be concluded that the subject device does 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 Xtrallux devices are assessed to be substantially equivalent to the predicate devices.