December 11, 2024

Foreo Inc.
% Danijela Domljanovic
Consultant
DD Consulting
401-4080 Living Arts Drive
Mississauga, ON L5B4N#
Canada

Re: K242747
Trade/Device Name: Faq™ (302)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 13, 2024
Received: September 12, 2024

Dear Danijela Domljanovic:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.12.11 17:37:39 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242747

Device Name
FAQ™ (302)

Indications for Use *(Describe)*
FAQ™ 302 is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of Ila-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of l-II and Fitzpatrick Classification of Skin Phototypes 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.

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510(k) Summary

Date of Summary Revision: 28-Aug-2024

1. Submitter's Identifications

Submitter's Name: FOREO Inc.

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Contact Person: Evan Feldstein

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2. Correspondent's Identifications

Correspondent's Name: DD Consulting

Address: 401-4080 Living Arts Drive, Mississauga, ON Canada

ZIP Code: L5B 4N3

Contact Person: Danijela Domljanovic

Contact Title: Regulatory Consultant

Contact E-mail Address: regulatoryna@foreo.com

Telephone: 647 928 6919

3. Name of the Device

Trade Name: FAQ

Model: FAQ 302

Regulation Number: 21 CFR 890.5500 Regulation

Name: Infrared Lamp

Common Name: Laser, Comb, Hair

Regulatory Class: Class II

Product Code: OAP

Review Panel: General & Plastic Surgery

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4. The Predicate Devices

Primary Predicate:	K210169	Hair Growth Device
Secondary Predicate:	K142573	HairMax LaserComb 41

5. Device Description

FAQ™ 302 is a handheld rechargeable square shaped device designed for improving hair growth with 20 laser diodes (wavelength 650±10nm) and 20 RED LED beads (640-660nm) on the inside surface.

By pressing the universal button, the user can power the device on, start treatment and change the intensity by quick-pressing the button again. Once the treatment is complete, the device is turned off by pressing and holding the universal power button for 3 seconds.

The device can also be connected wirelessly via Bluetooth to an FAQ App in order to manage treatment. After the treatment is completed, the device automatically powers off.

The device uses a non-detachable polymer lithium battery for power supply in compliance with IEC 62133-2:2017+A1:2021 standard.

6. Intended Use of Device

FAQ™ 302 is 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.

7. Comparison with Predicate Device

Table 1 Table Comparison of FAQ 302,LS-D601 (K210169) and HairMax LaserComb 41(K142573)

Features	Subject Device	Predicate Device	Predicate Device	Remarks
Regulatory Information				
Device Name	FAQ™ 302	Hair Growth Device	HairMax LaserComb 41	/

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510(K) No.	K242747	K210169	K142573	/
Regulation Number	890.5500	890.5500	890.5500	Same
Regulation name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Same
Regulatory Class	II	II	II	Same
Product Code	OAP	OAP	OAP	Same
Indications for Use	FAQ™ 302 is 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	The Hair Growth Device is 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 of1-II and Fitzpatrick Classification of Skin Phototypes I to IV.	The HairMax LaserComb 41 is indicated to treat Androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic alopecia and, promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.	Same
Treatment regimen	8 minutes every other day	25 minutes every other day	3 minutes per use, three times per week	Different **Note 1**
Use Environment	Home Use, over the counter	Home Use, over the counter	Home Use, over the counter	Same
Power Source(s)	Internal rechargeable Lithium battery	Power adapter	Internal rechargeable Lithium battery	Different **Note 2**
Maximum charging time	90 mins	Not applicable	Unknown	/
Electrical Power Source Frequency (Nominal)	60Hz	60 Hz	60 Hz	Same
Method of Channel Isolation	Type BF	Type BF	Type BF	Same
Automatic Shut Off	Yes	Yes	Yes	Same
Mode of operation	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes	Similar

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Output mode	Continuous light	Continuous light	Continuous light	Same
Classification according to IEC 60825-1	Class 3R	Class 3R	Class 3R	Same
Energy of per laser diode	<5mW	<5mW	<5mW	Same
Wavelength	Laser: 650±10nm Red light LED: 640-660nm	Laser: 650-660nm Red light LED: 640-660nm	Laser: 655±10nm	Similar
No. of light sources	Laser diodes: 20 lasers LED diodes: 20	Laser diodes: 26 lasers LED diodes: 30	Lasers LED diodes: 41	Different **Note 3**
Treatment Area	Approx. 32cm^2	Unknown	Approx. 40cm^2	Different **Note 3**

Comparison in Details

Note 1:

The proposed device treatment time is within the range of the predicate devices, and the treatment time of the proposed device does not raise new types of questions regarding safety and effectiveness.

Note 2:

Though the power source is different the proposed device was tested to applicable electrical performance standards.

Note 3:

The number of light sources, treatment area, wavelength, and intensity, are similar to the predicate devices, and do not raise new types of questions with regard to safety and effectiveness.

8. Non-Clinical Tests Performed:

Clinical testing was considered not to be needed for this 510(k).

The following non-clinical testing was provided in this 510(k):

Biocompatibility Testing

The subject device has been tested in compliance with the following standards and no additional risks concerning safety and effectiveness were noted;

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

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- ISO 10993-23 Biological evaluation of medical devices Part 23: Tests for irritation

Electrical Safety and Electromagnetic Compatibility Testing

Category	Standards	Standards Desc
Safety	IEC 60601-1:2005/AMD1:2012/AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	CAN/CSA-C22.2 NO. 60601-1:14	
	AAMI 60601-1:2005 + AMD 1:2012	
	IEC 60601-1-6:2010+ AMD1:2013 +AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	IEC 62366-1:2015+ AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
	IEC 60601-1-11:2015+AMD1:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
	IEC 60601-2-57: 2011	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
EMC	EN 60601-1-2: 2015 IEC 60601-1-2: 2014 (Edition 4)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
	IEC TR 60601-4-2:2016	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

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Software Verification and Validation

Software documentation consistent with Minor level of concern was submitted in this 510(k) per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Cybersecurity

The cybersecurity risks associated with the FAQ™ 302 were evaluated as follows:

- Identification of assets, threats, and vulnerabilities;
- Assessment of impact of threats and vulnerabilities on device functionality and end user;
- Assessment of the likelihood of threats and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk and risk acceptance criteria

The cybersecurity risk analysis performed, the controls identified, the comparison with the National Vulnerability Database, and the labeling information detailed with the Cybersecurity Assessment demonstrated that all risks associated with network capable interfaces of the device have been adequately mitigated.

9. Usability Study:

Usability validation testing was conducted with 15 adults enrolled to assure that the user could follow the directions we provided to safely use the device. Test results can be located in the "Usability validation report" that clearly indicate that the user instruction of FAQ 302 provides adequate guidance for the independent and appropriate home use for Laser and LED treatment.

10. Conclusion:

Based on comparison of intended use and technical characteristics, the subject device FAQ 302 is similar to the legally marketed predicate LS-D601. Hardware and software verification and validation demonstrated the FAQ 302 met all performance specifications.

Any differences between the FAQ 302 and the predicate devices do not raise new types of questions of safety and effectiveness. Therefore, the FAQ 302 is substantially equivalent to the predicate one.