October 13, 2022

Freedom Laser Therapy, Inc.
% Sharon Chen
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K222081
Trade/Device Name: ID-510 iRestore Elite
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 12, 2022
Received: July 15, 2022

Dear Sharon Chen:

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
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)*

K222081

Device Name

ID-510 iRestore Elite

Indications for Use *(Describe)*

The ID-510 iRestore Elite is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, 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.

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5. 510(k) Summary K222081

5.1 Submission Sponsor

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5.2 Submission Correspondent

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Contact: Sharon Chen
Title: Regulatory Consultant

5.3 Date Prepared

July 12, 2022

5.4 Device Identification

Trade Name:	ID-510 iRestore Elite
Classification Name:	Physical Medicine
Regulation Name:	Infrared Lamp
Regulation Number:	21 CFR 890.5500
Product Code:	OAP
Class:	Class II

5.5 Legally Marketed Predicate Device

Trade Name:	ID-500 iRestore Hair Growth System
510(k) Number:	K213094
Classification Name:	Physical Medicine
Regulation Name:	Infrared Lamp
Regulation Number:	21 CFR 890.5500
Product Code:	OAP
Class:	Class II

5.6 Reference Devices

iRestore Professional 282 (K183417), manufactured by Remax Medi-Tech (Shenzhen) Corporation

REVIAN RED (K173729), manufactured by PhotonMD, Inc.

Theradome LH40 (K180460), manufactured by Theradome, Inc.

Capillus 112, Capillus 244 (K192012), manufactured by Capillus

5.7 Indications for Use Statement

The ID-510 iRestore Elite is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.

5.8 Device Description

The ID-510 iRestore Elite is a low-level laser/light system operating at 680 ± 10, 655 ± 10, and 625± 10 nanometers. The physical configuration is that of a helmet containing an inner and outer liner, stabilized with a silicone pad lined fixation ring. The device helmet is constructed of an ABS type plastic. The system operates on line voltage at 100 or 240 volts. The helmet's inner liner permits full adjustment to any head shape by means of non-toxic silicone pads. The helmet contains 300 units of five-millwatt-diode lasers and 200 units of five-milliwatt, super luminescent diodes, that emit red light. This system delivers fixed laser emission levels, measured to be 2500 total millwatts per 12 minute treatment session, which cannot be altered by the operator.

5.9 Substantial Equivalence Discussion

The following table compares the ID-510 iRestore Elite to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5.1: Comparison of Characteristics

Attribute	ID-510 iRestore Elite	ID-500 iRestore Hair Growth System	iRestore Professional 282	REVIAN RED	Theradome LH40	Capillus 112, Capillus 244
Device Category	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
510(k) Number	Not applicable	K213094	K183417	K173729	K180460	K192012
Manufacturer	Remax Medi-Tech (Shenzhen) Corporation	Remax Medi-Tech (Shenzhen) Corporation	Remax Medi-Tech (Shenzhen) Corporation	PhotonMD, Inc.	Theradome, Inc.	Capillus
Product Code	OAP	OAP	OAP	OAP	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Indications for Use	The ID-510 iRestore Elite is indicated to promote hair growth in males who have Norwood-Hamilton Classifications	The predicate Is indicated to treat androgenetic alopecia for men and women. It is designed to promote hair growth in	The iRestore Professional 282 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-	REVIAN RED is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton	The Theradome LH40 (Theragrow) is an over the counter (OTC) therapeutic device intended to treat Androgenetic Alopecia and	The CapillusX and CapillusX+ laser domes are intended to treat Androgenetic Alopecia and promotion of hair growth in males who have Norwood

	of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.	males who have Norwood-Hamilton Classifications of Ila to V and in females who have Ludgwig-Savin Classifications of I to II. All users should also have Fitzpatrick Skin Types I to IV.	Savin Classifications of I-II, males who have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	Classifications of IIa - 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 patterns of hair loss; both with Fitzpatrick Skin. Types I - IV.	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; both with Fitzpatrick Skin Types I to IV.	Hamilton Classifications of IIA to V patterns of hair loss and treating Androgenetic Alopecia and promotion of hair growth in females who have Ludwig (Savin) Scale 1-4. II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.
OTC or Rx Only	OTC	OTC	OTC	OTC	OTC	OTC
Wavelength of LED	625 ± 10 nm and 655 ± 10 nm	655 ± 10 nm	655 ± 10 nm	620 – 660 nm	No LED	No LED
Wavelength of Laser	680 ± 10 nm	655 ± 10 nm	655 ± 10 nm	No laser	620 – 660 nm	678 ± 7 nm
Laser Power for Classification	Laser Class 3R	Laser Class 3R	Laser Class 3R	Not applicable	Laser Class 3R	Laser Class 3R
Time and Frequency of Treatment	12 minutes per treatment, to be used daily.	25 minutes per treatment, to be used every other day.	25 minutes per treatment, to be used every other day.	10 minutes per treatment, to be used daily.	20 minutes per treatment, to be used four times per week.	Six minutes per treatment, to be used daily.

5.10 Non-Clinical Performance Data

To demonstrate safety and effectiveness of ID-510 iRestore Elite and to show substantial equivalence to the predicate device, Remax Medi-Tech (Shenzhen) Corporation completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The ID-510 iRestore Elite passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Electrical safety testing per ANSI AMMI 60601-1 – Passed
- Electromagnetic Disturbance (EMC) testing per IEC 60601-1-2 – Passed
- Software verification and validation per FDA Guidance – Compliant
- Lifetime Testing – Supports lifetime of five years

- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained

5.11 Statement of Substantial Equivalence

The ID-510 iRestore Elite has the same indications for use as the ID-500 iRestore Hair Growth System. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, ID-510 iRestore Elite has been determined to be substantially equivalent to ID-500 iRestore Hair Growth System.