Freedom Laser Therapy, Inc.
Mr. Raymond Blanche
Consultant
NST Consultants, Inc.
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

May 17, 2019

Re: K183417
Trade/Device Name: iRestore Professional 282
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 21, 2018
Received: March 20, 2019

Dear Raymond Blanche:

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,

For Jennifer Stevenson,
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183417

Device Name
iRestore Professional 282

Indications for Use *(Describe)*
The iRestore Professional 282 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-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.

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

Freedom Laser Therapy, Inc.

Submitter's Contact Information

Name:	Raymond R. Blanche
Address	NST Consultants, Inc 641 Shunpike Road, Suite 311 Chatham, NJ 07928
Telephone: Facsimile:	(973) 539-7444 (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name:	iRestore Professional 282
Sponsor Contact Information:	Craig Nabat Freedom Laser Therapy, Inc. 16782 Von Karman Avenue, Unit #15 Irvine, CA 92606 T. 714-669-9888 F. 714-730-9989
Common or Usual Name:	Lamp, non-heating, for promotion of hair growth
Classification Name:	Infrared lamp per 21 CFR 890.5500
Classification Code:	OAP (Laser, comb, hair)

Predicate Devices:

Device Trade Name	Manufacturer
iRestore Hair Growth System K151662	Remax Medi-Tech Corporation

Reference Devices:

HairMax Lasercap K180885	Lexington International

Date Prepared: May 15, 2019

Intended Use / Indications for Use

The iRestore Professional 282 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-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.

Technological Characteristics

The iRestore Professional 282 consists of 82 red visible light, diode lasers and 200 red light super-luminescent diodes configured within an outer helmet and protective inner liner. The use of diode lasers and non-laser LEDs provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.

Performance Data:

No clinical performance data was produced for this submission because the iRestore Professional 282 is a device similar in optical, electronic and mechanical function as well as recommended clinical treatment regime, to the predicate device, the **iRestore Hair Growth System K151662.** There is one design distinction between the two systems. The iRestore Professional 282 contains an increased number of laser didoes and LEDs over the iRestore Hair Growth System.

The iRestore Professional 282 was tested to internationally recognized standards, consistent with the current recommendations adopted by the FDA.

1. IEC 60825-1 Edition 2.0 2007 - 03 Laser Safety & Classification
2. IEC 60601-1:2005 (currently called AAMI/ANSI standard) Basic Safety and Essential Performance
3. IEC 60601-1-2 Edition 1.0. 2010 -04 EMC. This replaces Edition 3.0 2007 - 03
4. IEC 60601-1-11 Edition 1.0 2014 – 06 Home Use. This replaces Edition 2010 – 04
5. IEC 62304 Edition 1.1 2015 – 06 Software and Life Cycle Processes
6. ISO 14971 Second edition 2007 – 03 – 01 Application of Risk Management to Medical Devices
7. ISO 10993-1 2009 (R) 2013 – Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process.
   ISO 10993-10:2010/(R) 2014 –Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.

Over – The – Counter Testing Program

To test volunteer subjects for the suitability of the iRestore Professional 282, 30 subjects were asked twenty-six questions, after being provided a standard retail package and a full owner's manual. The test subjects was given as long as they required to read and understand the product packaging and manual. No assistance was provided to them and they were not permitted to ask any questions of the interviewer. The interviewer then conducted the interview and filled in the responses from the subjects. The subjects were required to answer all questions correctly to be counted as PASS for the correct Self Selection or, to have made the correct decision to purchase the product or not; to assemble and use the product correctly and comprehend the hazards and maintenance procedures for the device. These decisions would be based upon their understanding of the Intended Use of the product and the manual.

If the questions were answered correctly, they were given a P for PASS. If any questions were answered incorrectly, they were given an F for FAIL. The number of subjects required to answer all questions correctly is 24 of 30 for a 80% success rate.

The results of the Over-the-Counter testing demonstrate that the iRestore Professional 282 comply with the requirements the FDA determined to be applicable. The test revealed an overall **90% pass rate** for the subject group of 30 male and female participants. The testing further demonstrates that age, education, socioeconomic group, race or medical hair loss status are not variants that prevent proper self-selection, usability and comprehension of hazards and maintenance procedures for the average consumer to successfully navigate the purchasing and use process of the iRestore Professional 282**.**

Based on this data, the sponsor believes that the iRestore Professional 282 for male and female users has met the requirements for OTC sale.

Substantial Equivalence

The iRestore Professional 282 device is similar to the device known as the iRestore Hair Growth System, FDA Cleared under K151662. It is as safe and effective as the predicate device.

Both systems, which use red light diode lasers and/or the equivalent, super-luminescent, light emitting diodes are classified as class IIIa/3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same. The sponsor believes that the difference in the physical appearance or in the method of delivering the radiant energy of the two systems is essentially the same and does not alter the safety profile. Finally, the comparative data summarized in the 510(k) notice confirms the safety and efficacy of the iRestore Professional 282 for OTC Use, according to Part 21 CFR 801 Subpart C. For these reasons, the iRestore Professional 282 satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

Treatment Protocol

The iRestore Professional 282 and the iRestore Hair Growth System possess the same treatment regime of 25 minutes, every other day, on non-consecutive days, for 16 weeks.

The following Comparison Chart in support of substantial equivalence is provided:

iRestore Professional 282 (Proposed)	**iRestore Hair Growth System** (K**151662)**
LLLT Device Type	LLLT Device Type
OTC Application	OTC Application
Intended Use - Androgenetic Alopecia	Intended Use - Androgenetic Alopecia
Contain Laser Diodes-82 Class 3R	Contain Laser Diodes-21 Class 3R
Contain LEDs, 200, SMD	Contain LEDs, 30, 5mm, Thru-the-Hole
Helmet Design	Helmet Design
650 nm +/- 10nm.	650 nm +/- 10nm
Marketing Clearance –Females & Males, OTC	Marketing Clearance –Females & Males, OTC
Passive Use-Hands Free	Passive Use-Hands Free
OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp
General & Plastic Surgery Committee	General & Plastic Surgery Committee
Skin Phototypes - I- IV	Skin Phototypes - I- IV
Hamilton-Norwood IIa-V Hair Loss Classification Ludwig-Savin I – II Hair Loss Classification	Hamilton-Norwood IIa-V Hair Loss Classification Ludwig-Savin I – II Hair Loss Classification
Treatment- 16 weeks, for 25 minute treatment times, three times a week on alternate days	Treatment- 16 weeks, for 25 minute treatment times, three times a week on alternate days
Device Class II	Device Class II

Conclusion

With the data presented in the Comparison Chart, the sponsor believes that this demonstrates the iRestore Professional 282, is substantially equivalent to the iRestore Hair Growth System based upon the equivalent technological designs of the compared devices, the sponsor requests the FDA to clear the device via the 510(k) notice.