DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 6, 2016

Freedom Laser Therapy, Inc.
% Raymond Blanche
Managing Member
NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

Re: K151662
Trade/Device Name: iRestore
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 6, 2015
Received: December 8, 2015

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151662

Device Name
iRestore Hair Growth System (Model ID-500)

Indications for Use *(Describe)*
The iRestore Hair Growth System 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 lla- 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.

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

Freedom Laser Therapy, Inc.

Submitter's Contact Information

Name:	Raymond R. Blanche
Address	NST Consulting, LLC 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 Hair Growth System
Sponsor Contact Information:	Craig Nabat Freedom Laser Therapy, Inc. 7815 Beverly Blvd., 3rd Fl. Los Angeles, CA 90036

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
igrow II Hair Growth System	Apira Science, Inc.

Reference Devices:

None

Date Prepared: Revision January 6, 2016

Intended Use / Indications for Use

The iRestore Hair Growth System 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 Hair Growth System consists of 21 red visible light, diode lasers and 30 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 is an IDENTICAL device in optical, electronic and mechanical function as well as recommended clinical treatment regime, to the predicate device, the **igrow.** There is one ergonomic design distinction between the two systems. The iRestore is not configured with, audio capability through attached ear phones.

Substantial Equivalence

The iRestore device is IDENTICAL to the device known as the igrow Hair Growth System cleared under 510(k) numbers K141567 and K140931. 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 of no consequence and does not effect the therapeutic value or the safety profile. The lack of ear phones in the iRestore has no significance in the comparative process between the NEW device and the predicate.

Finally, the clinical data summarized in the 510(k) notice confirms the safety and efficacy of the iRestore Hair Growth System for OTC Use, according to Part 21 CFR 801 Subpart C). For these reasons, the iRestore Hair Growth System satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

Treatment Protocol

The iRestore and the igrow devices possess the same treatment regime of 25 minutes, every other day, on non-consecutive days, for 16 weeks. This treatment regime has been established through clinical testing with the igrow device, in separate male and female cohort clinical trials. The data from these trials was published in a peer review journal. The references are as follows:

1. The Growth of Human Scalp Hair Mediated by Visible Red Light Laser and LED Sources in Males. Lasers in Surgery and Medicine 45:487–495 (2013)
2. The Growth of Human Scalp Hair in Females Using Visible Red Light Laser and LED Sources. Lasers in Surgery and Medicine 46:601–607 (2014)

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

iRestore Hair Growth System	**igrow Hair Growth System**
LLLT Device Type	Identical
OTC Application	Identical
Intended Use - Androgenetic Alopecia	Identical
Contain Laser Diodes-21 Class 3R	Identical
Contain LEDs, 30 5mm, Thru-The-Hole	Identical
Helmet Design	Identical
655 NMS.	Identical
Marketing Clearance –Females & Males, OTC	Identical
Passive Use-Hands Free	Identical
OAP Classification	Identical
Classification Name -Infrared Lamp	Identical
Common Usage Name - Lamp, Non-Heating	Identical
General & Plastic Surgery Committee	Identical
Skin Phototypes - I- IV	Identical
Hamilton-Norwood IIa-V Hair Loss Classification Ludwig-Savin I – II Hair Loss Classification	Identical Identical
Efficacy Rates - High Compared to Placebo	Identical
Treatment- 16 weeks, every other day	Identical
Device Class II	Identical

With the data presented in the Comparison Chart, the sponsor believes that the this data demonstrates that red light lasers in class IIIa/3R, used in the iRestore Hair Growth System, are substantially equivalent to the igrow Hair Growth system and based on the IDENTICAL technological designs of the two devices, the sponsor requests the FDA to clear the device via the 510(k) notice.