March 25, 2020

Conversion Labs PR LLC
% Raymond R Blanche
Consultant
NST Consultants, Inc.
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

Re: K193667
Trade/Device Name: Shapiro MD, Model Laser 272
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: October 30, 2019
Received: December 31, 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/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,

Jessica Mavadia-Shukla, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* K193667

Device Name
Shapiro MD, Model Laser 272

Indications for Use *(Describe)*
The Shapiro MD, Model Laser 272 is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton Classifications of IIa - V, or females with androgenic alopecia who have Ludwig-Savin Classifications I - II, and for both, with Fitzpatrick Skin Phototypes I- 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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K193667

510(k) Summary
Shapiro MD, Model Laser 272

Submitter's Contact Information

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Address	NST Consultants, Inc. 641 Shunpike Road, Suite 311 Chatham, NJ 07928
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Name of Device and Name/Address of Sponsor

Trade Name:	Shapiro MD, Model Laser 272
Sponsor Contact Information:	Stefan Galluppi –CTO, COO Conversion Labs PR LLC D/B/A Shapiro MD 53 Calle Palmeras, Suite 802 San Juan, Puerto Rico, 00901 Telephone: 866-351-5907

Date Prepared: March 19, 2020

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: Diode Laser Cap (K173678), Cosmo Far East Technology Limited

Device Description

The Shapiro MD, Model Laser 272 is a dome-shaped low level laser therapy (LLLT) device designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of 272 visible red light-emitting diodes at 650nm and 5mW each. The Cap is designed with an outer plastic cover and a protective inner liner (containing the electronics and laser array) and is powered by an included battery pack.

Intended Use / Indications for Use

The Shapiro MD, Model Laser 272 is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton Classifications of Ila-V, or females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and for both, with Fitzpatrick Skin Phototypes I-IV.

Technological Characteristics
The Shapiro MD, Model Laser 272 contains the listed number of diode lasers configured within an outer cap helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head i.e., the area commonly covered with stylized hair. The Shapiro MD, Model Laser 272 is powered by a lithium-ion battery pack that contains an embedded controller chip. In all other area of design, manufacturing, and aesthetic appearance, the devices are identical, as they are private labeled by the manufacturer Cosmo Far East Technology Limited.

Performance Data:
No clinical performance data was submitted because the Shapiro MD, Model Laser 272 is the same device as the predicate, the Diode Laser Cap, cleared under Kl 73678. The proposed device and predicate devices are IDENTICAL and the same device is offered for PRIVATE LABEL by the manufacturer. They are the same device in optical, electronic, mechanical function and aesthetic appearance, as well as the same recommended clinical treatment regime. The sponsor Conversion Labs PR LLC has chosen to use the identical User Manual as the manufacturer. Only the logo and color graphics have been altered. A page by pages analysis supports this use.

Substantial Equivalence
Shapiro MD, Model Laser 272 is the same device as the predicate, the Diode Laser Cap, cleared under Kl73678, with 272 visible red light-emitting diodes at 650nm and 5mW each. Both devices have identical indications for use, treatment regiment, and technological and design characteristics, as noted below.

Treatment Protocol
The Shapiro, Model Laser 272 and the identified predicate, possess the same treatment regime of 30 minutes, every other day, on non-consecutive days, for the initial treatment regime of 16 weeks.

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

	Shapiro MD, Model Laser 272	Diode Laser 272
LLLT Device Type	Laser Diode	Laser diode
Use Application	OTC	OTC
Intended Use Androgenetic Alopecia	Androgenic Alopecia	Androgenic Alopecia
Contain Laser Diodes-Class 3R	272, 5 milliwatts each.	272, 5 milliwatts each
Physical Design of Device	Helmet	Helmet
Wavelength	650+/-5 NMS.	650+/-5 NMS.
Marketing Clearance	For females and males, OTC	For females and males, OTC
Use Type	Passive Use-Hands Free	Passive Use-Hands Free
Classification Code	OAP	OAP
Classification Name	Infrared Lamp	Infrared Lamp
Common Usage Name	Lamp, Non-Heating	Lamp, Non-Heating
Classification Panel	General & Plastic Surgery	General & Plastic Surgery
Skin Phototypes	I- IV	I- IV
Hair Loss Classification	Norwood-Hamilton IIa-V for males Ludwig-Savin I – II for females	Norwood-Hamilton IIa-V for males Ludwig-Savin I – II Hair for females
Treatment Regime	16 weeks, for 30 minute treatment times three times a week, on alternate days.	16 weeks, for 30 minute treatment times three times a week, on alternate days.
Device Class	II	II

Over – The – Counter Testing Program

No OTC testing was performed for this submission because the User Manual and packing for the subject device are same as in the predicate. The only exception is color and logo of the subject device literature. The graphic changes do not alter the content of the User Manual, the key variable in any OTC testing evaluation.

Non-Clinical Testing Performance

The Shapiro MD, Model Laser 272, conforms to the following international consensus standards:

1. IEC 60601-1:2005 + CORR. 1: 2006 + CORR. 2: 2007 + A1: 2012 Medical Electrical Equipment- Part 1: General Requirements for Basic Safety and Essential Performance
2. IEC 60601-1-2: 2014 Medical Electrical Equipment - Part 1-2 General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances-Requirements and Tests.
3. ISO 10993-5 2009 Biological Evaluation of Medical Devices Part 5 Tests for In Vitro Cytotoxicity, ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
4. IEC 60825-1 Edition 2.0 2007 - 03 Laser Safety & Classification
5. IEC 62133 Battery Cells and IEC60950 for the Battery Charger

Conclusion

Based on the technical comparisons between the Shapiro MD, Model Laser 272 and the identified predicate it can be concluded that the Shapiro MD, Model Laser 272 is identical to the predicate device in technical specifications. Since the Shapiro MD, Model Laser 272 is manufactured using the identical

platform with no difference between models, it can be concluded that the Shapiro MD, Model Laser 272 is equally safe. Indications for use of the two devices are also identical. Therefore, it can be determined that the Shapiro MD, Model Laser 272 is Substantially Equivalent to the identified predicate.