DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 8, 2017

Liaoning Sidey Optoelectronics Technologies Co., Ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25
Banbidian Rd., Liyuan Town, Tongzhou
Beijing, 101121 CN

Re: K163173
Trade/Device Name: Handheld Diode Laser For Hair Removal
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: November 7, 2016
Received: November 14, 2016

Dear Ray Wang:

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,

Jennifer R. Stevenson -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)*
K163173

Device Name
Handheld Diode Laser for Hair Removal

Indications for Use *(Describe)*
The Handheld Diode Laser for Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Handheld Diode Laser for Hair Removal is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

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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"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."

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163173

1. Date of Preparation

   11/07/2016

2. Sponsor

Liaoning Sidey Optoelectronics Technologies Co., Ltd.

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Handheld Diode Laser for Hair Removal
Common Name: Light Based Over-The-Counter Hair Removal
Model(s): SD-BD01

Regulatory Information:
Classification Name: Light Based Over-The-Counter Hair Removal
Classification: II;
Product Code: OHT;
Regulation Number: 21 CFR 878.4810;
Review Panel: General & Plastic Surgery;

Intended Use Statement:
The Handheld Diode Laser for Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Handheld Diode Laser for Hair Removal is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

5. Device Description

The Handheld Diode Laser for Hair Removal is an Over-The-Counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. The device is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime permanent hair reduction is defined as long term, stale reduction in the number of hairs regrowing when measured out of 6, 9, and 12 months after the completion of the treatment regimen.

The Handheld Diode Laser for Hair Removal is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 808nm.

Laser hair removal is based on the principles of selective photothermolysis (SPTL): a combination of the appropriate laser wavelength, pulse duration, and fluence can obtain optimal effect on a targeted tissue with minimal effect on surrounding tissue.

Wavelengths of 808 nanometers (nm) are widely used in hair removal treatment, it is selectively absorbed by melanin in the hair shaft, damaging the follicular epithelium, and further causes hair loss, while the competing chromophores (oxyhemoglobin and water) absorb less energy at these wavelengths.

6. Identification of Predicate Device

Predicate 1#:
510(k) Number: K120737
Product Name: TRIA Laser Hair Removal System
Manufacturer: Tria Beauty, Inc.

Predicate 2#:
510(k) Number: K142845
Product Name: SILKPRO Laser Hair Removal System
Manufacturer: Wuhan Lotuxs Technology Company, Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for medical device equipment and medical electrical systems used in the home healthcare environment.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Performance Testing for Spot Size Accuracy.

A Usability/Label Comprehension Study was conducted.
Two smaller groups out of these participants were chosen to participate in a usability study in which the actual product along with its labeling would be tested.
The first group of 13 participants consisted of 7 females, 6 males and their ages ranged from 19-71 years. Two participants with dark skin tone and one participant with blond hair were included in this group. It was explained to them what the study was all about and then were asked (two at a time) to pretend that they had just purchased the product and were to use it for the first.

The tester allowed ample time for the users to read/study the labeling, include information on retail box, name plate and Instruction Manual Rev: V 1.02, completely while recording questions and answering them. Then the actual use of the product was observed, remarks and questions were recorded.

Then we revised the Instruction Manual form Rev: V 1.02 to Rev: V 1.03 according with the question from the tester.

A second group of 10 participants was chosen for a second test. There were 5 females, 5 males and their ages ranged between 19 and 73 years.

Again, after allowing ample time to read and study the Instruction Manual Rev: V 1.03, the questions asked came down to only 2 and they were not pertaining to safety or operation.

Results

For the first groups,

1) All participants understood the “Skin Tone Chart”, Warnings, Indications and Contraindications;
2) Three user refused to use the product after reading the determination as “Skin Tone Chart” and Indications, because skin tone and hair color;
3) 9 of the remaining 10 users had questions.

The inputs of the first groups needed some changes and additions to the Instruction Manual (Rev: V 1.02).

For the second groups, the result showed that all (100%) participants were able to properly use the device and properly clean it with the labeling submitted.

The inputs of the second test groups did not warrant any more changes and additions to the Instruction Manual (Rev: V 1.03).

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device**	**Predicate Device** K120737	**Predicate Device** K142845	**Remark**
Product Code	OHT	GEX	OHT	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	The Handheld Diode Laser for Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Handheld Diode Laser for Hair Removal is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.	The TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.	The SILKPRO is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.	SE
Prescription/OTC	OTC	OTC	OTC	SE
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	SE

Table 2 Performance Comparison

Item	**Proposed Device**	**Predicate Device** K120737	**Predicate Device** K142845	**Remark**
Laser Type	Diode Laser	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	Class IV	SE
Laser Wavelength	808 nm	810 nm	810 nm	SE
Spot Size	Ø9mm (Round)	Ø10mm (Round)	9x9 mm	Discussion 1
Fluence	5.5 - 21.2 J/cm^2	7-22 J/cm^2	5 - 25 J/cm^2	SE
	5.5 J/cm^2, 11 J/cm^2, 16.5 J/cm^2, 21.2 J/cm^2	6 J/cm^2, 10 J/cm^2, 14 J/cm^2, 18 J/cm^2, 22 J/cm^2	5 J/cm^2, 10 J/cm^2, 15 J/cm^2, 20 J/cm^2, 25 J/cm^2	Discussion 2
Power Supply	AC 110V/50Hz-60Hz	100-240 V 50/60Hz	100-240 V 50/60Hz	SE

Discussion 1

The proposed device is different in Spot Size from the predicate, the proposed devices' pulse duration range is cover the predicates' and both proposed device and predicate has same Fluence, therefore, this difference will not affect the substantially equivalency.

Discussion 2

The proposed device is different in fluence setting level from the predicate, the proposed devices' pulse duration range is cover the predicates' and both proposed device and predicate has same Fluence, therefore, this difference will not affect the substantially equivalency.

Table 3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Sapphire in handpiece and handpiece tip (Stainless Steel)	Stainless steel and Sapphire in handpiece	SE
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	SE
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.