April 6, 2020

Beijing Sano Laser S&T Development Co., Ltd
% Huifang Zhao
Consultant
Microkn Business Consulting (Shanghai)Co., Ltd
Room 1319, Block A, No 3699, Gonghexin Road, Jingan District
Shanghai, 200435 CN

Re: K191970
Trade/Device Name: Diode Laser Hair Removal System
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: GEX
Dated: March 5, 2020
Received: March 5, 2020

Dear Huifang Zhao:

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)*
K191970

Device Name
Diode Laser Hair Removal System

Indications for Use *(Describe)*
The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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.

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K191970

510(k) Summary

Date Prepared: 4/5/2020

1. Contact Information

1.1. Applicant

Applicant Name:	Beijing Sano Laser S&T Development Co., Ltd.
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1.2. Consultant

Company:	Microkn Business Consulting (Shanghai) Co., Ltd.
Address:	Room 1319, Block A, No 3699, Gonghexin Road, Jingan District, Shanghai, China
Contact Person:	Huifang Zhao
Telephone:	+86 13961151430
Email:	huifang.zhao@microkn.com

2. Device information

Trade Name:	Diode Laser Hair Removal System
Common Name:	Powered Laser Surgical Instrument
Model(s):	P-808, P-808L, P-808S, P-808W
Classification:	II
Product Code:	GEX
Regulation:	21 CFR 878.4810

3. Legally Marketed Primary Predicate Device

Product name:	Diode Laser Therapy Machine
510(k) Number:	K161692
Product Code:	GEX
Manufacture:	Beijing ADSS Development Co., Ltd

4. Device Description

The proposed device, Diode Laser Hair Removal System, is a surgical device, which is intended for hair removal, permanent hair reduction on all Fitzpatrick skin types.

There are 4 models included, P-808, P-808L, P-808S and P-808W, the four models have same intended use, mechanism of action, principle and specification, only difference is the configuration. The detailed difference shown in Table 1.

Table 1 the Difference of Models

Model	**P-808**	**P-808L**	**P-808S**	**P-808W**
Size (cm)	46×36×105	45×37×110	47×36×113	47×32×112
Size of LED screen (inch)	10	10	12	10

The main components of proposed device are shown in **Table 2.**

Table 2 Main Components of Proposed Device

Components	**Function Description**	**Applied Model(s)**
Handpiece	Deliver the laser to area to be treated	All Models
Touch screen	The user interface and for controlling of the system	All Models
Emergency stop switch	Stop the system in case of emergency situation	All Models
Key switch	Start the system	All Models
LED screen	Display the working status of the system, set the treatment parameters	All Models
Foot switch	control the laser output	All Models

5. Indications for Use

The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

6. Substantially Equivalent (SE) Comparison

The Diode Laser Hair Removal System has been carefully compared to legally marketed devices with respect to intended use, configuration, principle of operation (Table 3), and performance specifications (Table 4).

Table 3 General Comparison

Item	Proposed Device	Predicate Device	Remark
Product Code	GEX	GEX	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Diode Laser Therapy Machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	SE, with difference in wording, while the actual indications are the same.

Configuration	Main Unit	Main Unit	SE
	Handpiece	Handpiece	SE
	Foot Control	Foot Control	SE
Principle of Operation	Diode Laser	Diode Laser	SE

Table 4 Performance Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
Laser Type	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	SE
Spot Size	1.44 cm^2	1.44 cm^2	SE
Fluence	10-120 J/cm2	2-120 J/cm2	Discussion 1
Frequency	0.5-10 Hz	1-10 Hz	SE
Power Supply AC	110V/60Hz	110 V/50 Hz-60 Hz	SE

Discussion 1

The proposed device is different from the predicate device in fluence value, but the proposed device's fluence value range is included in the predicate's fluence value. Therefore, this difference will not affect the substantially equivalency.

Safety comparison has been done to validate the EMC, biocompatibility specification and safety of the device (Table 5).

Table 5 Safety Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Sapphire in handpiece and handpiece tip (Stainless Steel)	Sapphire in handpiece and handpiece tip (Stainless Steel)	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Skin sensitization	No evidence of sensitization	No evidence of sensitization	SE
Irritation	No evidence of irritation	No evidence of irritation	SE
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

7. Non-Clinical Testing

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 60601-2-22:2012, 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 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests;
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity;
- ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1: Performance Testing for Spot Size Accuracy and Energy Output Accuracy.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

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