November 7, 2022

Sanhe Laserconn Tech Co., Ltd.
% Gary Wang
Q&R Consultant
Bonnier Quality Supervision Consulting (JM) Center
Hailunxinyuan No.3203, Jianghai District
Jiangmen, Guangdong 529000
China

Re: K222800
Trade/Device Name: Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A)
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: September 8, 2022
Received: September 16, 2022

Dear Gary 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. 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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222800

Device Name
Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A)

Indications for Use *(Describe)*
Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) 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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510(k) Summary

Date: 10-21-2022（M/D/Y）

In accordance to 21 CFR 807.92 regulation, the following summary of information is provided:

I Applicant/Manufacturer

Sanhe Laserconn Tech Co., Ltd.
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Contact Person

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Ⅱ Submitter/Correspondent

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Contact Person

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Ⅲ Device Regulation Information

Common Name of Device:	Powered Laser Surgical Instrument
Classification panel:	General & Plastic Surgery
Classification Names:	Laser Surgical Instrument for Use in General and Plastic Surgery and In Dermatology
Regulation Number:	21 CFR 878.4810
Regulation Class:	II
Product Code:	GEX
Type of 510(k) submission:	Traditional 510(k)
Model Name/Number	Milestone Smart-M, Milestone Standard-A
Device Trade Name	Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A)

Ⅳ Predicate Device Information

Predicate Device 1

Sponsor:	Alma Lasers, Inc.
Device Name:	SOPRANO ICE MULTI-APPLICATION & MULTI-TECHNOLOGY PLATFORM
510(K) Number:	K140009

Predicate Device 2

Sponsor:	Beijing Kes Biology Technology CO., LTD.
Device Name:	Diode laser therapy system
510(K) Number:	K210168

V Device Description

Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) is solution for fast hair removal with 810nm±10nm high power laser diodes. They are designed with TEC and sapphire cooling unit for skin contact. The laser beam is sublimated with a patented technology of beam shaping for a high efficiency for hair removal solution. This diode laser hair removal can be used for Fitzpatrick skin type I-VI. The pulse energy is up to 40J/cm^2.

VI Indications for Use

Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) 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.

VII Compatibility

Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) does not connect with any other device and does not connect network during normal operation. So will not cause any problem related to compatibility with other device and network. For EMC, the devices were tested according to IEC 60601-1-2:2014.

VIII Technological Comparison

Pls refer to the later part： Substantial Equivalence Comparison Table 1

IX Software

Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) includes software which are interface between operator and device. The risk analysis and control to software is done, the Level of Concern is classified as Moderate LOC. The validation to software is done according to FDA Final Guidance-General Principles of Software Validation and confirm the software does not raise unacceptable risk by Sanhe Laserconn Tech Co., Ltd.

X. Summary of Verification Tests

All verification tests have been performed according to below standard, the testing results are passed

1.AAMI/ANSI ES60601-1:2005(R) 2012 and 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 safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

3.ISO 10993-5:2009: Biological evaluation of medical devices. Part 5-Tests for in vitro cytotoxicity.

4.ISO 10993-10:2010 Biological evaluation of medical devices, Part 10-Tests for irritation and skin sensitization.

5.IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

6.IEC 60601-2-22:2019 for use in conjunction with AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

7.Software embedded in medical device was validated by the least burdensome approach according to FDA Final Guidance-General Principles of Software Validation.

8.IEC62304-2015 Medical device software – Software life cycle processes

9.ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

Bench testing was conducted to demonstrate that system operation, wavelength, single pulse laser energy, repetition frequency, laser power output, and cooling parameters met specified requirements. The test results also show that both models Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) have achieved the expected results and satisfied the standards listed above.

XI.Conclusion:

Based on the SE comparison and software validation result, Sanhe Laserconn Tech Co., Ltd. considers Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A) does not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.

Substantial Equivalence Comparison Table 1				
Description	**Predicate Device 1**	**Predicate Device 2**	**Subject Device**	**Discussion**
K number	K140009	K210168	K222800	
Device name	SOPRANO ICE MULTI-APPLICATION & MULTI-TECHNOLOGY PLATFORM	Diode laser therapy system	Diode Laser Hair Removal Systems for Medical Use (Models: Milestone Smart-M, Milestone Standard-A)	
Manufacturer	Alma Lasers, Inc.	Beijing Kes Biology Technology CO., LTD.	Sanhe Laserconn Tech Co., Ltd.	
Prescription	Yes	Yes	Yes	Same
Over-the-Counter use	No	No	No	Same
Product Code	GEX	GEX	GEX	Same
Configuration	Main console Unit	Main Unit	Main Unit	Same
	Modules	Handle	Handle	Same
Laser Type	Diode Laser	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Class IV	Same
Regulatory Class	Class II	Class II	Class II	Same
Wavelength	810nm(nominal)	808nm(nominal)	810nm(nominal)	Discussion 1
Spot Size	12 mm×10 mm=1.2 cm2	12 mm×12 mm=1.44 cm2	10 mm×10 mm=1.0 cm2	Discussion 2
Fluence	2-20 J/cm2 (SHR), 2-120 J/cm2 (HR)	10-125 J/cm2	1-40 J/cm2	Discussion 3
Pulse Duration	3.3-200 ms	10-400 ms	3-160 ms	Discussion 4
Frequency	5-10 Hz (SHR), 0.5-3 Hz (HR)	1-10 Hz	1-10 Hz	Discussion 5

Tissue Cooling	Contact continuous, thermo-electrical	Aluminum contact, close-cycle water cooling	Sapphire Contact and TEC Cooling	Discussion 6
Power Supply	Unknown	99V-121V, 50/60Hz 1400VA	AC 100~240V/50/60Hz 1500VA	Discussion7
Biocompatibility	Unknown	Comply with ISO 10993-5, ISO 10993-10	Comply with ISO 10993-5 ISO 10993-10	Discussion 8
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-1, IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-1 IEC 60601-2-22 IEC 60825-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Storage temperature	Unknown	Unknown	5℃-55℃	Discussion 9
Operation temperature	Unknown	Unknown	5℃-30℃	Discussion 11
Operating humidity	Unknown	Unknown	≤80%	Discussion 12
Dimension	6.69*4.8*1.9 [inches]	450×430×1000(mm)	464*387*979(mm) (Milestone Standard-A) 437*355*233(mm) (Milestone Smart-M)	Discussion 13
Weight	Unknown	52kg	46.1kg (Milestone Standard-A) 18.2kg (Milestone Smart-M)	Discussion 14

Discussion1: Different - Wavelength

The laser wavelength of this device is the same as K140009 and similar to K210168.

According to" IEC 60825-1:2014 Safety of laser products Part 1: Equipment classification and requirements 700nm~1050nm laser is the emission limit of the same group, so the slight wavelength difference between 808nm and 810nm will not make a difference in laser safety. In addition, the therapeutic effect of laser treatment is caused by the thermal effect generated after the laser penetrates the skin surface and is absorbed by hair follicles However, according to the laser absorption curve of human tissues, the wavelength range from 800nm to 850nm belongs to the low value of water absorption and the peak value of pigment absorption. Therefore, the subtle wavelength difference between 808nm and 810nm will not have any difference in the penetration depth of laser and the absorption effect of tissues, and will not affect the clinical effectiveness.

Discussion2: Different - Spot Size

The spot size for the proposed device is similar to the predicate device. The output laser energy density is an important factor affecting safety. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Discussion 3: Different – Fluence Laser energy density is low and safety is better.

Discussion 4: Different - Pulse Duration

The pulse width of this instrument is smaller than that of K210168 and K140009, and the single pulse energy density is lower, so the safety is better.

Discussion 5: Different - Frequency

The pulse frequency of this instrument is the same as K210168, higher than K140009.

The product of laser repetition frequency and pulse energy of the therapeutic instrument is not more than 100W. For example, when the frequency is 10HZ, the corresponding energy density is 10J/cm^2, which is slightly less than the single pulse energy value of K140009 of 120 J/cm^2 and K210168 of 125 J/cm^2. Therefore, the safety and effectiveness will not be affected.

Discussion 6: Different -Tissue Cooling

Good skin cooling can greatly reduce the probability and severity of skin damage from laser energy. This device is same as model K140009, the sapphire on the handle tip is cooled by TEC. It's with smaller size, lighter weight, fast cooling speed, the good cooling result will improve the treatment safety.

Discussion 7: Different - Power Supply

The power supply of the device may be different from the predictive device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this power supply. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Discussion 8-14: The differences from Discussion 8-14 don’t affect the safety and performance to medical device.