July 3, 2023

Ivylaser (Beijing) Technology Co., Ltd.
% Eva Li
Consultant
Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Room 901, No. 889, Pinglu Road, Jing'an District
Shanghai (Shanghai Jing'an HUAFA Center)
Shanghai, 200435
China

Re: K230025
Trade/Device Name: IVYLASER Handhold Hair Removal Machine
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: January 4, 2023
Received: January 4, 2023

Dear Eva Li:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230025

Device Name
IVYLASER Handhold Hair Removal Machine

Indications for Use *(Describe)*
IVYLASER Handhold Hair Removal Machine is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. IVYLASER is also intended for permanent hair reduction 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

K230025

1. Contact information

1.1. Applicant

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1.2. Consultant

Company: Microkn Medical Technology Service (Shanghai) Co., Ltd.

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Contact Person: Heather. Wang

Telephone: +86 13166194697

Email: heather.wang@microkn.com

2. Device information

- Trade Name: IVYLASER Handhold Hair Removal Machine
- Model(s): iyoung mini-P, iyoung mini-GY, iyoung mini-GN
- Classification: II
- Product Code: OHT
- Regulation Number: 21 CFR. 878.4810

3. Intended use/Indications for Use

IVYLASER Handhold Hair Removal Machine is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. IVYLASER is also intended for permanent hair reduction 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.

4. Legally Marketed Predicate Device

Product name: SILKPRO Laser Hair Removal System

510(k) Number: K142845

Product Code: OHT

Manufacture: Wuhan Lotuxs Technology Co., Ltd.

5. Description of the device

The proposed device is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. It is also intended for permanent hair reduction

Three models (iyoung mini-P, iyoung mini-GY, iyoung mini-GN) are included in IVYLASER Handhold Hair Removal Machine series products, and they have the same intended purposes and working theories.

The main components list of proposed device shown in **Table 1**.

Table 1 Main Components list of Proposed Device

Description	**Quantity**	**Function Description**
Device host	1	For removing hair from the body.
Power adapter	1	Provides stable current and voltage.

6. 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 Medical electrical device Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60825-1 Safety of laser products -Part 1: Equipment classification and requirements
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

7.Clinical Test Conclusion

No clinical study is included in this submission.

8.Predicate Devices

Product name: SILKPRO Laser Hair Removal System

510(k) Number: K142845

Product Code: OHT

Manufacture: Wuhan Lotuxs Technology Co., Ltd.

9.Substantially Equivalent (SE) Comparison

The IVYLASER Handhold Hair Removal Machine has been carefully compared to legally marketed devices with respect to intended use, configuration, performance comparison **(Table 2)**, physical specifications comparison **(Table 3)** and safety comparison **(Table 4)**.

Table 1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Product Code	OHT	OHT	SE
510K Number	K230025	K142845	/
Classification Name	Laser Instrument, Surgical, Powered	Laser Instrument, Surgical, Powered	SE
Regulation	21 CFR 878.4810	21 CFR 878.4810	SE

Number			
Panel	General & Plastic Surgery	General & Plastic Surgery	SE
Class	Class II	Class II	SE
Intended Use	IVYLASER Handhold Hair Removal Machine is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. IVYLASER is also intended for permanent hair reduction 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.	SILKPRO laser hair removal system adopts the 810nm diode laser, which targets on the hair follicle and slows the process of hair growth. It is used to remove unwanted hair of body. SILKPRO is also intended for permanent hair reduction 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 intended use are the same.

Indications for Use	IVYLASER Handhold Hair Removal Machine is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. IVYLASER is also intended for permanent hair reduction 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.	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 hair reduction 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

Table 2 Performance Comparison

Item	Proposed Device	Predicate Device	Remark
Laser Type	Diode Laser	Diode Laser	SE
Wavelength	808nm	810nm	Discussion 1

Max Energy Density (Per Sec)	15.43 J/cm^2	25J/cm^2	Discussion 2
Energy Density (Per Sec)	1.85 J/cm^2, 3.09 J/cm^2, 6.17J/cm^2, 9.26 J/cm^2, 15.43 J/cm^2	5J/cm^2, 10J/cm^2, 15J/cm^2, 20J/cm^2, 25J/cm^2	Discussion 2
Laser Beam	9mm×18mm	9mm×9mm	Discussion 2
Pulse Width	Maximum: 600ms Minimum: 50ms	Maximum: 408.1ms Minimum: 68.06ms	Discussion 3
Frequency	Maximum: 5hz Minimum: 0.5hz	Maximum: 1hz Minimum: 0.24hz	Discussion 3

Table 3 Physical Specifications Comparison

Item	Proposed Device	Predicate Device	Remark
Operating Environment	Temperature: 5~28℃; Humidity: <70%	Temperature: +5℃~+40℃; Humidity: ≤80%	Discussion 4
Storage Environment	Temperature: 10℃～30℃; Humidity: 30%～75%; Atmospheric pressure：860hPa～1060hPa	Temperature: -40℃～+55℃; Humidity: ≤ 90%; Atmospheric pressure：700～1060hPa	Discussion 4
Input Voltage	100～240V, 50/60Hz	100～240V,	SE

		50/60Hz	
Usability	Button operation	Button operation	SE

Discussion 1

The Proposed Device uses a wavelength of 808nm. The device is safe for human body according to IEC 60825-1 test report, report details please refer to VOL_017.

Discussion 2

There are some differences on the energy density and laser beam between proposed device and predicate device. The laser beam of the proposed device is larger than that of the predicate device. However, the energy density is lower of the proposed device, and both of the devices comply with IEC 60825-1. Therefore, the safety and effectiveness won't be affected and they can be considered substantially equivalent in safety and effectiveness.

Discussion 3

The proposed device is different in pulse width and frequency from the predicate device. But the energy density of the proposed device is lower than the predicate device and both of the devices comply with IEC 60825-1. Therefore, the safety and effectiveness won't be affected and they can be considered substantially equivalent in safety and effectiveness.

Discussion 4

There are some differences on the operating and storage environment between proposed device and predicate device. But the proposed device has passed the transportation test according to ASTM D4169-2016 and shelf life verification test, details please refer to VOL_014. Therefore, the safety and effectiveness won't be affected and they can be considered substantially equivalent in safety and effectiveness.

Safety comparison has been done to validate the biocompatibility specification, EMC and safety of the device (Table 4).

Table 4 Safety Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
Biocompatibility			
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	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser safety	Comply with IEC 60825-1	Comply with IEC 60825-1	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.