November 18, 2021

Glan Electronics Co., Ltd.
℅ Iris Fung
Official Correspondent
SGS-CSTC Standards Technical Services Co., LTD
198 Kezhu Road, ScienTech Park Guangzhou Economic & Tech
Development District
GuangZhou, Guangdong
China

Re: K213041
Trade/Device Name: IPL Hair Removal, Model: OBT-02
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: September 14, 2021
Received: September 22, 2021

Dear Iris Fung:

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 and Part 809); 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,

Purva Pandya
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)*
K213041

Device Name
IPL Hair Removal, Model: OBT-02

Indications for Use *(Describe)*
The IPL Hair Removal Device OBT-02 Version is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults.

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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Date of the summary prepared: November 2, 2021

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor

- Company Name: Glan Electronics Co., Ltd.
- Address: A4 Building, Huafa Industrial Zone, Fuyuan 1st Road, Xinhe Community, Fuyong Town, Bao'an District, Shenzhen, China
- Phone: 0086-755-28910840
- Contact Person (including title): LISA PAN
- E-mail: lisa@glancap.com / lisa@glanelectronics.com

Application Correspondent:

- SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Iris Fung
- Tel: + 86-32136908
- Email: Iris.Fung@sgs.com / jianda-lee@foxmail.com

2. Subject Device Information

Trade Name:	IPL Hair Removal, Model: OBT-02
Common Name:	Light Based Over-The-Counter Hair Removal
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Review Panel:	General & Plastic Surgery
Product Code:	OHT
Regulation Class:	2
Regulation Number:	878.4810

3. Predicate Device Information

Sponsor	Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.	STETIC MEDICAL AESTHETICS DEVELOPMENT (SHENZHEN) CO., LTD	CyDen Limited.
Device Name	IPL Salon Hair Reduction System	DUO	iPulse SmoothSkin Gold Hair Removal System
510(k) Number	K181568	K161565	K160968
Product Code	OHT	ONF, OHT	OHT, GEX
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	2	2	2

4. Device Description

IPL Hair Removal, Model: OBT-02, a small over-the-counter device, is a home-use device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. A personal Light-Based Hair Removal System. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. Emission activation is by finger switch. Device includes IPL DEVICE, Power supply and User manual. It is used AC Powered (100-240 V AC). The weight of the device is 220g, and the size is 150 x 75 x 45mm (H*W*D). The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

5. Intended Use / Indications for Use

The IPL Hair Removal Device OBT-02 Version is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults.

6. Test Summary

6.1 IPL Hair Removal, Model: OBT-02 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012, IEC 60601-1-11:2015 and IEC 60601-2-57:2011 standards
- Electromagnetic compatibility test according to IEC 60601-1-2:2014 standard
- Biocompatibility test according to ISO10993-5; ISO 10993-10 Standard

- Software verification and validation test according to the requirements of the FDA "Guidance for PreMarket Submissions and for Software Contained in Medical Devices"
- Bench performance testing conducted to demonstrate that the pulse duration, output energy, maximum fluence, and wavelength do not deviate in excess of the allotted 10% tolerance

6.2 **Materials**

There is one part of patient- directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
IPL Lamp output window and case enclosure	ABS	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)

We provide ISO 10993-5, ISO 10993 -10 test reports for the following biocompatibility evaluation.

- In-Vitro Cytotoxicity Testing
- Skin Sensitization Testing
- Skin Irritation Testing

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL Hair Removal, Model: OBT-02 is the same or similar to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III
Device Name and Model	IPL Hair Removal, Model: OBT-02	IPL Salon Hair Reduction System, Model: F60001	DUO, Model: IPLHH380-IT	iPulse SmoothSkin Gold Hair Removal System
510(k) Number	K213041	K181568	K161565	K160968
Manufacturer	Glan Electronics Co., Ltd.	Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.	STETIC MEDICAL AESTHETICS DEVELOPMENT (SHENZHEN) CO., LTD	CyDen Limited.

Sponsor: *Glan Electronics Co., Ltd.*

Subject Device: *IPL Hair Removal, Model: OBT-02*

510(k) number: *K213041*

Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Predicate Device III**
Intended Use	The IPL Hair Removal Device OBT-02 Version is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults.	The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. And 12 months after the completion of a treatment regimen.	The DUO (Model: IPLHH380-IT) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. The DUO is also intended for permanent reduction in unwanted hair. 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 regimen.	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold is also indicated for the permanent reduction in hair regrowth, 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.
Source Energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	AC Mains
'Use' Classification	OTC	OTC	OTC	OTC
Device Classification	Class II	Class II	Class II	Class II
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Wavelength (nm)	510nm~1100nm	475nm~1200nm	480nm~1200nm	510nm~1100nm
Max. Fluence (J/cm^2)	Max 4.0 [Joules/cm^2]	Max 5 [Joules/cm^2]	5 [Joules/cm^2]	6 [Joules/cm^2]
Spot Size (cm^2)	3.0 cm^2	1.72 cm^2 or 3.02 cm^2	3 [cm^2]	3 [cm^2]
Light Intensity	Level 1: 1.5 J/cm^2 Level 2: 1.9 J/cm^2 Level 3: 2.6 J/cm^2 Level 4: 3.7 J/cm^2 Level 5: 4.0 J/cm^2	Level 1: 2.8 J/cm^2 Level 2: 3.1 J/cm^2 Level 3: 3.5 J/cm^2 Level 4: 3.8 J/cm^2 Level 5: 4.2 J/cm^2	Level 1: 1.33 J/cm^2 Level 2: 1.57 J/cm^2 Level 3: 1.80 J/cm^2 Level 4: 1.97 J/cm^2 Level 5: 2.23 J/cm^2	3 - 6 J/cm^2
Pulse duration	3 ms	11-12 ms	＜20 milliseconds	2-10 ms
Skin contact	Yes	Yes	Yes	Yes

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III
sensor				
Skin tone sensor	Yes	Yes	Yes	Yes
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch
Number of Output Channels	One channel	One channel	One channel	One channel
Output Intensity Level	5 levels	5 levels	5 levels	--
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes
60601Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57，	Yes Comply with IEC 60601-1 and IEC 60601-1-2,IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC62471
Compliance* with 21 CFR 898	No	No	No	No
Weight	220g	650g	280g	--
Dimensions	150*75*45 mm(H*W*D)	143*69.5*43mm(H*W*D)	130*70*30 mm(H*W*D)	--
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5, ISO 10993-12 and ISO10993-10 requirements.
Electrical Safety	Comply with IEC60601-1 and IEC60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1

Finial Conclusion:

Based on the nonclinical testing conducted, the subject device “IPL Hair Removal, Model: OBT-02” is as safe, as effective, and performs as well as the legally marketed predicate devices.