December 1, 2023

Hebei Zhemai Technology Co.,Ltd
Ray Wang
Official Correspondent
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Langfang, Hebei 065201
China

Re: K232708
Trade/Device Name: Intense pulsed light therapy device
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: ONF
Dated: September 4, 2023
Received: September 5, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
2023.12.01 15:06:55 -05'00'

Tanisha Hithe
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

Tab#15 User Manual

Intense pulsed light therapy device

Model: FI-L06

User Manual

Caution: Federal law restricts this device to sale by or on the order of a physician.

Hebei Zhemai Technology Co.,Ltd

Catalogue

Foreword

You are welcome to use the Intense pulsed light therapy device. The Intense pulsed light therapy device produced by our company is a high-tech product independently developed by our company and has independent intellectual property rights.
This manual is applicable to the Intense pulsed light therapy device,the model is FI-L06.
After receiving the device, first check the accessories according to the packaging label. If the accessories delivered with the device are incomplete, please contact us according to the contact information in Chapter 8.

 User Notice

If you are using the Intense pulsed light therapy device for the first time, be sure to read this manual carefully before powering up.
It is recommended not to use this device in the presence of electromagnetic interference, vibration and other disturbing environmental conditions. During use, this device will not interfere with other instruments/device.
Avoid using this Intense pulsed light device in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen. When there is enough oxygen in the air, some materials, such as cotton and wool, are easily ignited by the high temperatures generated by the normal operation of an Intense pulsed light device. Solvents and flammable solutions used for cleaning or sterilization should evaporate before using the laser device.
The discarded parts produced by scrapping or replacing the Intense pulsed light therapy device should be sent to the designated institution or manufacturer for professional treatment to avoid polluting the environment.
The power supply device should be grounded reliably.

Special Note

Warning

Intense pulsed light therapy device can emit high-intensity infrared laser beams, and in order to protect the eyes, users and patients are required to wear appropriate safety goggles in accordance with (NOHD) standards.

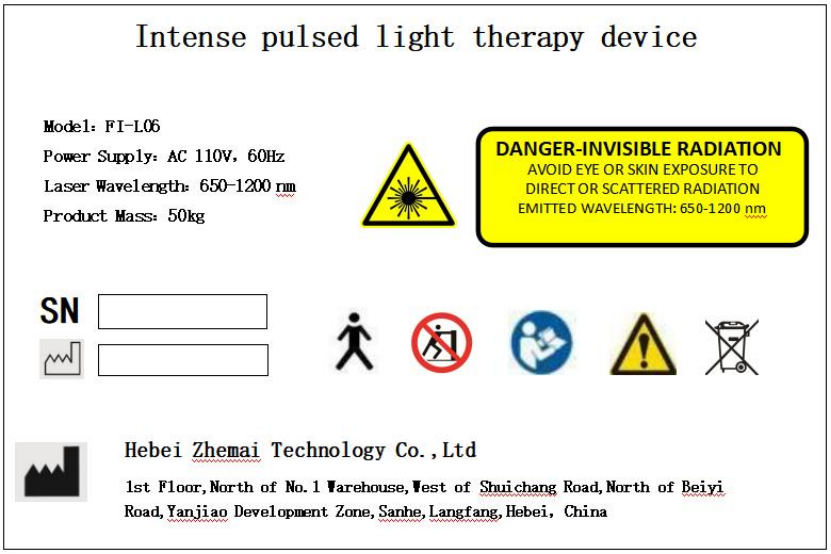
Please note the following:

Do not point the laser directly at the eyes and skin.

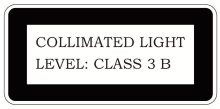
When the device is working, do not cut off the power.

Be sure to familiarize yourself with the structure and specifications of the device before use.

Chapter 1 Symbol Description



Number	Symbol	Interpretation
1		Manufacturer
2		Manufacturing Date
3	SN	Serial Number
4		General warning signs
5		Do not throw away electrical and electronic products at will, and dispose of them separately in the designated garbage area
6		Type BF applied part The applied components meet the requirements of the standard IEC 60601-1 to provide protection against electric shock, especially regarding the leakage current not greater than the value of human injury
7		Laser Output Warning Label
8		No Pushing

9		Laser radiation label
10		Follow the user manual
11		Key switch
12		Emergency stop switch
13		Medical Device Labels for Restricted Sale
14		Foot pedal
15		Emergency Stop Switch Label
16		Up label
17		Fragile label
18		Keep dry
19		Don't scroll

Chapter 2 Clinical Application

2.1 Indication For Use

The Intense pulsed light therapy device is indicated for use in surgical and aesthetic applications in permanent hair removal.

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.

2.2 Clinical features

This product has novel design, stable operation, short irradiation time, lasting effect, convenient operation, good clinical effect and high safety factor.

Convenience: Human-machine interface - touch screen, intuitive and easy to use, so its operation is simple and convenient.

Permanent Hair Removal: It is suitable for hair of all skin tones and has a good hair removal effect.

Safety: stable performance, long service life, and real-time control by intelligent microprocessor.

2.3 Potential risks

The most common complications of Intense pulsed light therapy device are postoperative local erythema and follicular edema, most of which resolve spontaneously within a few hours. Rare complications are localized crusting, purpura, blisters, hyperpigmentation or hypopigmentation, and increased sebum production. Adverse reactions after hair removal are mainly related to energy density and epidermal melanin content, and are also significantly related to seasonal changes, treatment sites, and solar radiation. Adhering to preoperative and postoperative guidance and correct operation can reduce adverse reactions.

2.4 Processing method

(The following processing steps and methods are for reference only, the actual parameters and operating procedures are subject to clinical use)

2.4.1 Preoperative preparation

1) For patients with dark skin, sun radiation should be avoided as much as possible before surgery. It is best to use sunscreen for 4 to 6 weeks. For those with a tendency to pigmentation, hydroquinone can be added to prevent it.
2) The treated area must be skin-prepared prior to treatment, so hair, oil and dirt should be thoroughly shaved.

2.4.2 Anesthesia

Whether anesthesia is required during treatment should be determined according to the treatment site and size, whether it is a sensitive area, and the patient's pain. Generally, only topical anesthesia can be used.

2.5 Clinical considerations

1) Generally closely related to energy density, treatment outcome and inflammatory status after skin damage. High energy density is more effective, but at the same time, the inflammatory response is greater; the deep skin is also damaged. The energy is processed starting at low energy and gradually increasing the energy density until better results are achieved.
2) The maximum energy allowed is inversely proportional to the skin pigment. Generally, the skin is darker and has a lower energy density to reduce the absorption of more light energy into heat by the epidermis. A good cooling system is very important to the treatment, to protect the skin from burns to the greatest extent, and it is better for dark skin.
3) Shave excess hair before surgery, as excess hair absorbs energy and heats it on the epidermis, which may cause partial skin burns and damage the probe.
4) A good cooling system will reduce the temperature of the skin. Cold probes help to increase allowable energy density and partial anesthesia. Cooling is highly recommended throughout the treatment, especially for darker skin. Dark skin absorbs energy more easily than light skin.

2.6 Intense pulse light handle cleaning

When the treatment is complete, remove the handle, clean the top of the handle with a relatively soft cotton cloth and keep it dry.

1) Cleaning process

   After processing is complete, exit the operating program and turn off the power of the device. Soak a soft cotton cloth in 75% alcohol and wipe the top of the handle clean until the alcohol has evaporated again. Then wipe the surface marks with the soft cotton cloth.

2) Warning message

   Intense pulsed light processing precision optical components, please avoid falling and make them subject to blunt force impact or not allowed to open, otherwise the intense pulse light module will not emit light normally; This is a large impact of the intense pulse light output. The surface cleanliness of the optical crystal, therefore, before use Inspection and proper cleaning. The handle transfer system should avoid serious damage caused by bending during use.

2.7 Contraindications

- Tanned skin (has been exposed to the sun or used tanning beds in the past three to four

weeks) or has recently used a self-tanning lotion

- Diseases stimulated by light (Lupus, Epilepsy…)
- Use of photosensitizing medications such as: tetracycline or herbal (St John's Wort) etc.
- Use of anticoagulants or has a history of bleeding coagulopathies.
- Fragile and dry skin. Use of Accutane (isotrenoin) Roaccutane or Tretinoin – Retin A for the treatment of acne in the previous 6-12 months.
- Active infections: herpetic lesions, cold sores (place on anti-viral medication pre-treatment)
- Any inflammatory skin condition (e.g. eczema, etc.), in the area to be treated.
- Pregnancy or trying to conceive.
- Tattoos, permanent make-up, suspicious pigmented lesions (can treat around them)
- History of keloidal scarring
- For Hair Reduction - Electrolysis, waxing or plucking in last 6 weeks (target has been removed)
- Planning to be in the sun following treatment
- Diabetes (unless under control)
- Cancer, in particular, skin cancer
- Hormonal Disorders (unless under control)

Chapter 3 Technical Parameters

3.1 Technical parameters

Model	FI-L06
Light source	Intense pulsed light
LCD screen	LCD touch screen 7 inches
Wavelength	650nm-1200nm
Spot size	3.2cm^2 (8mm×40mm^2)
Pulse length	0.1-25ms
Energy density	1-50J/cm^2
Pulse-frequency	1-10Hz
Cooling	Air cooling+water cooling
Input voltage	110V 60Hz
size	89.6*57.7*94.3cm (package) 79*49*95cm (device)
weight	50kg (device) 65kg (package)

3.2 Conditions of use

3.2.1 Working conditions:

a) Ambient temperature range: 15℃~30℃;

b) Relative humidity range: ≤80%;

c) Atmospheric pressure range: 860hPa~1060hPa;

d) Power supply: AC 110V, 60Hz.

3.2.2 Transportation and storage environment

a) Do not place the product in a separate enclosure unless proper ventilation is provided;

b) No insulation;

c) Keep away from chemical substances and corrosive substances;

d) Dustproof;

e) Special protection controller (LCD screen), handle and crystal, fragile, no pressure.

3.2.3 Shelf Life

5 years

Note: The maximum IPL emission number (maximum IPL lens flash) of xenon lamp tube before performance degradation is 100000 times.

3.3 Electromagnetic Interference

The Intense pulsed light therapy device complies with IEC 60601-1-2 "Electromagnetic Compatibility requirements and tests". Part of IEC 60601-1-2 addresses the issue of unintended RF emissions from products. Accidental emissions from products may interfere with the performance of other nearby equipment. Emissions from Intense pulsed light therapy device have been reduced to practical levels without affecting function. If interference from an intense pulsed light therapy device is suspected, ensure that the intense pulsed light therapy device is plugged into an AC power source not shared by the affected device. If the interference persists, move the Intense pulsed light therapy device or affected equipment to another room.

Chapter 4 Working Principle

4.1 System principle

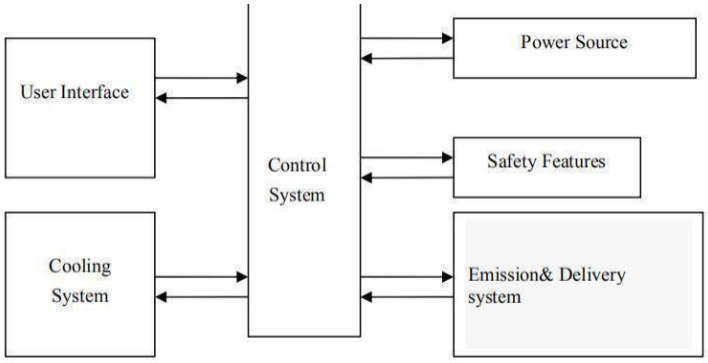
Intense pulsed light is a non-laser light source, which is incoherent light composed of single or multiple pulse sequences, and has the characteristics of wide spectral range and high energy density. The light source of the Intense pulsed light therapy device is a xenon lamp. Its basic working principle is that the trigger applies a high voltage to the xenon gas to trigger the ionization of the xenon gas. Internal xenon avalanche ionization, xenon converts and releases the charged energy in the form of high-intensity light radiation, and this discharge process is a pulse.

The parameters required in the treatment process, such as energy density, etc., should be set by the user according to the actual situation.

4.2 System

The Intense pulsed light therapy device consists of six modules, namely control system, user interface, power supply, laser emission and delivery system, cooling system and safety features. As shown in Figure 4.1.

Figure 4.1 Block Diagram of Intense pulsed light therapy device System



4.2.1 Control system

The control system consists of a microprocessor, a control circuit and a detection circuit. The control module is highly automated. Users need to turn on the power switch, the key switch, and release the emergency switch. After the system is turned on, the system will automatically perform system self-checking, processing parameter calls and other actions. After system initialization, self-checking, and parameter calling, press the foot switch and the control module will adjust it. The pulse parameters of each release energy, and alarm when the system is abnormal.

4.2.2 User Interface

The display module is mainly composed of a touch screen and a liquid crystal display. The touch screen consists of a touch detection component and a touch screen controller. The touch detection component is installed on the front of the LCD to detect the user's touch position and

send it to the touch screen controller after receiving. The main function of the touch screen is to receive touch information, convert it into the coordinates of the touch point, and then send it to the CPU, where it can receive and execute commands from the CPU. And finally realize the man-machine operation display.

4.2.3 Power

The power module is mainly composed of photon pulse power, DC 12V switching power supply and energy storage capacity. The photon power consists of a charging part, a pre-burning part of the xenon lamp and a discharging part. The DC 12V switching power supply converts input AC to output DC, providing DC 12V power for fans and semiconductor cooling parts.

4.2.4 Intense pulsed light emission and delivery system

In the standby state, when the switch button on the handle is triggered, the xenon lamp will emit a strong pulse of light through the light spot emission window on the handle.

4.2.5 Cooling system

The cooling system consists of a fan and a water circulation system. After the device is turned on, the cooling system starts to work. The fans air-cool the electrical components of the main unit and the insulated distributor, removing heat generated by the airflow within the machine. The internal circulating water is replaced in time and takes away the heat generated by the processing handle, and is sent to the water temperature cooling system.

4.2.6 Security Features

Intense pulsed light therapy device provides enough safety features to ensure the normal operation of the system, such as key switch, emergency stop switch, internal safety interlock, protective casing and alarm system to immediately shut down the system in an emergency, press the red mushroom Shaped emergency stop switch to terminate IPL energy discharge. The red switch is used to turn off the power in an emergency. Press it and the power can now be turned off. After turning clockwise, the machine will continue to work. Or the machine keeps shutting down.

The Intense pulsed light therapy device contains a "normally closed" safety shutter that prevents IPL emission when in the closed position. The shutter will only open when the system is in ready mode and the foot switch is pressed.

The alarm system consists of buzzer alarm and symbol alarm. Detailed warnings and faults are described below.

Water flow alarm: there is no water or no water circulation inside, the indicator light is displayed, and the alarm sound follows. In response, the machine will immediately stop all work.

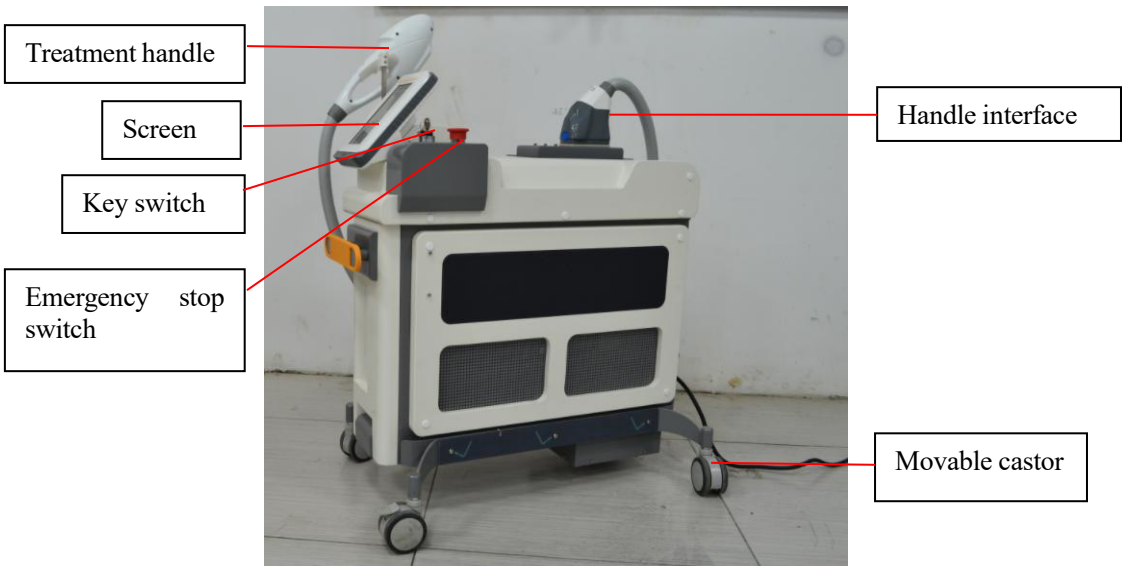
Water temperature alarm: when the temperature is higher than the system setting: 55 ℃, the indicator light shows this, and an alarm sound is issued at the same time. In response, the machine will immediately stop all work.

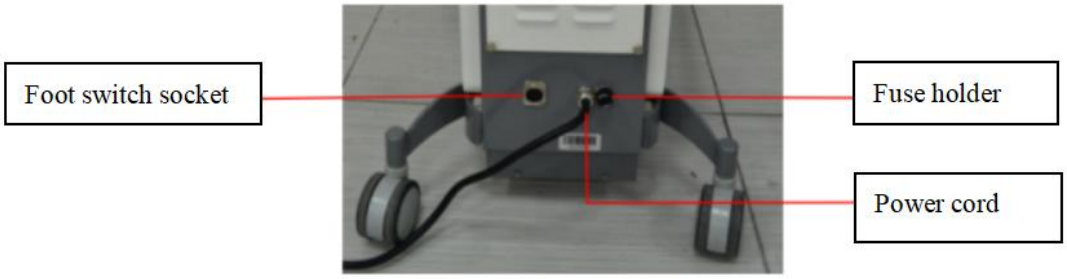
Chapter 5 Installation and Commissioning

Installation and commissioning of device must be done by qualified professionals and technicians trained by the manufacturer.

5.1 Model FI-L06

5.1.1 Accessories

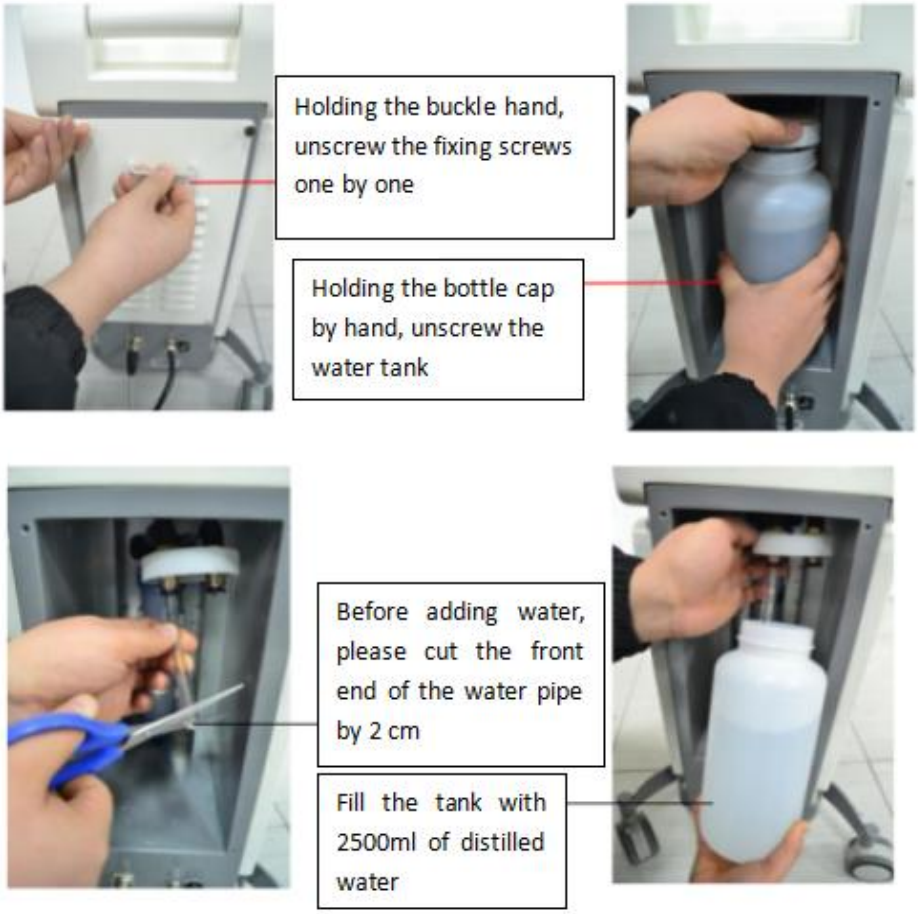


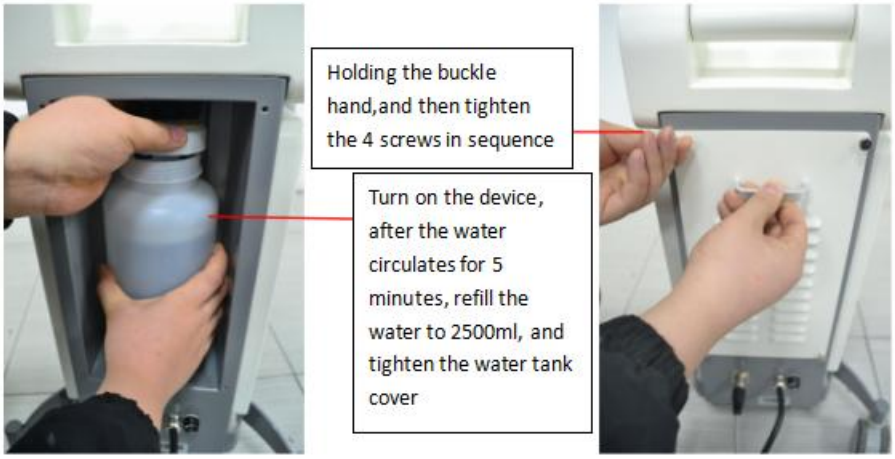


5.1.2 Accessories of the device

5.1.3 Water inlet procedure

Open the rear of the device as shown below





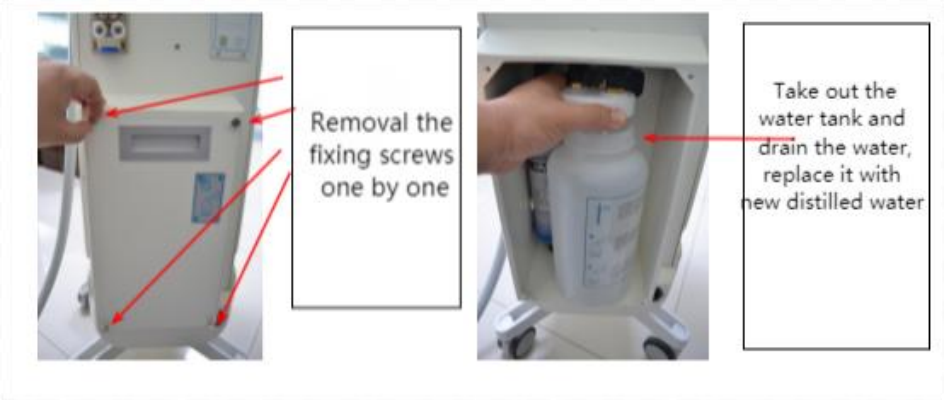
5.1.4 Connect the pedals as shown below.

5.1.5 After the above operations are completed, please connect offline.

Method: The water contact CPC on the treatment handle plug points to the water CPC socket. The method is the same as connecting the power system. When you hear the sound "pa" twice, it means the connection is successful. As follows.

5.1.6 After inserting the therapy handle, turn on the power, then turn the power emergency switch and the key switch to ensure the machine is powered on.

5.1.7 Change the water every 2 or 3 months, here's how to drain it.



5.1.8 Handle connection

Insert the handle socket until a "click" sound means a good handle connection.

Chapter 6 Instructions for Use

6.1 General Instructions

The Intense pulsed light therapy device is an intense pulsed light system that provides intense pulsed light in the wavelength range of 650nm-1200nm. Intense pulsed light (IPL) therapy device employ the principle of selective thermal decomposition. That is, thermal damage to the target chromophore is achieved by using light of an appropriate wavelength in a pulse that exceeds the thermal relaxation time of the chromophore, but by limiting the pulse width below the thermal relaxation time of the skin. Thermal damage to the target chromophore is caused by using light of an appropriate wavelength, but preserving normal skin by limiting the pulse width to a pulse width below the skin's thermal relaxation time.

Intense pulsed light differ from lasers in that they provide multiple wavelengths in each light pulse, rather than just one. In general, IPL enhances penetration without using excessive energy levels and is able to target specific chromophores. Based on this, the Intense pulsed light therapy device is indicated for use in surgical and aesthetic applications in permanent hair removal.

WARNING：HAZARDOUS EXPOSURE IF THE CONTROLS AND REGULATIONS ARE NOT USED OR PERFORMED IN THE SPECIFIC METHODS OF THE LASER SYSTEM BEFORE USE OR OPERATION.

6.2 Start the program

Once filled with water, proceed as follows：

1) Check that the handle adapter is plugged into the treatment head of the device. (Note： The handle must be connected to the specified position above, otherwise the device will operate incorrectly.)
2) Check that the foot switch is also connected to the field marked "foot switch".
3) After the above steps 1 and 2 are completed, insert the three-core power plug into an AC110V socket that can withstand the corresponding current.
4) Turn on the rocker switch on the back of the chassis, rotate the key clockwise from "off" 90 degrees to "on", then turn the emergency stop switch to the right to enter the release state, at this time the hair removal instrument is turned on, and the touch screen displays the startup image.
5) After waiting for a few minutes, the Intense pulsed light therapy device will automatically complete the preheating and enter the standby mode screen. (If there is a problem with the

cooling system, the temperature cannot be controlled to increase to the specified temperature, it is regarded as a device failure, the device cannot enter standby mode, and always remains in the initial startup image).

6.3 System Control

6.3.1 Initial interface and main interface

Figure 1 Startup interface, enter Figure 2 after 2 seconds

Figure 2 Enter the language options: select English and enter Figure 3

Figure 3 Enter the automatic protection detection of the instrument, enter Figure 4 after 10 seconds

Enter the function options, select the treatment item and enter Figure 4

Figure 4 Work interface, parameter adjustment settings

1） 

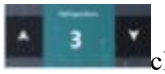
Click the energy button 

choose  increase energy,  reduce energy

2） 

Click the energy button 

choose  flip up mode,  flip down mode

3） 

click  Increase cooling intensity, click  Reduce cooling intensity

4）Click  button to enter the working state, click again to enter the standby state

5） 

The temporary counter shown here is used to count the number of glows, and will be zero when returning to the main interface where the device is turned off

6） 

Water temperature detection

7） 

The total number of luminous counts is used here to permanently save the total usage times.

6.3.2 Parameter adjustment settings

The appropriate therapeutic parameters were selected according to the required treatment mode and patient status.

Chapter 7 Maintenance

7.1 System maintenance

System repairs should be performed by a Zheone certified service engineer. For training and information, please contact your local Zheone representative.

7.2 Cleaning and Disinfection

7.2.1 Cleaning external surfaces

The outside of the IPL can be cleaned with a soft cloth moist with mild soapy water solution, do not use harsh detergent. To disinfect the exterior of the laser system, wipe it with a soft cloth stained with 75% medical alcohol. Cleaning frequency should be once a week, in frequent use can be appropriate to increase the cleaning frequency.

Warn

Do not attempt to access any internal components. Electrical shock and/or accidental laser exposure may result. Do not spray or pour 75% medical alcohol directly on the system console.

7.2.2 Cleaning the system touch screen display clean the system touch screen display with a damp soft cloth

Warn

Do not spray or pour 75% medical alcohol directly onto the system console or control screen, or you may damage the console, touch screen, and system electronics.

7.2.3 Cleaning the handle

7.2.3.1 Cleaning the protective windows

The protective window is an optical device. Essentially, with use, it breaks down, and once broken, the protective window must be replaced. However, inspection and cleaning after each procedure will extend its life.

Warn

Hair from the patient may collect on the windows. During treatment, windows may need to be washed regularly. This window must be cleaned using the techniques described below.

Cautious

If the window is not properly maintained, debris can build up on the surface of the window, causing permanent damage to the window and ultimately to the phone optics.

Warn

Before checking the window, the system must be shut down. Always wear the correct glasses when the system is on. Serious eye injury can occur in the event of an accidental laser emission.

Notice

Stick and cotton applicator are needed, but do not use products that contain adhesives.

λ Make sure the system is turned off.

λ If necessary, place a small amount of 75% medical alcohol on a cotton swab; Shake excess alcohol off the cotton swab before cleaning the protective window.

λ Gently wipe the surface of the window.

λ Check the window. If necessary, clean the window again with a new cotton-tipped applicator.

Notice

Windows must be kept clean before treating patients. Chips, pits, cracks, or burns in Windows are not acceptable. Windows with these abnormalities must be replaced. If the exception on the window cannot be resolved, you must replace the window.

7.2.3.2 Tips for cleaning your phone

Sterilize patients who use 75% medical alcohol. Windows should be cleaned as described in "Cleaning Protective Windows".

Warn

Before disinfecting the handle tips, make sure the system is turned off or in standby mode. Always wear appropriate protective glasses when the system is turned on. If accidental laser emission occurs, it can cause serious damage to the eyes.

7.2.4 Handling of handle components

For infection control reasons, disinfecting the handle and then disposed of according to local agency policies and procedures.

7.3 Calibration procedure

If self-calibration fails, Zheone authorized personnel should perform the following calibration. Questions regarding this procedure should be directed to your local Zheone representative.

Disclaimer Warning

Calibration is a service procedure and can only be performed by a Zheone-certified service engineer or a customer who has attended and passed a Zheone-certified service training course. Adjustments by anyone other than a trained Zheone service engineer or certified customer will void any existing manufacturer's warranty on the instrument.

A service manual for this system can be purchased from the Zheone Microservice Department, however, possession of service instructions or service tools does not authorize the repair or modification of the Zheone Microsystem by non-certified personnel.

7.3.1 Equipment

- λ Laser safety glasses for everyone in the room (produces the appropriate optimum density at the wavelength).
- λ Lambda laser energy meter, the meter used must have received a NIST traceable calibration or a calibration to an applicable standard (international) within the past 12 months (in the U.S.).

7.3.2 Calibration Instructions

- λ Places the laser energy meter in a convenient location so that the sensor head can be easily accessed with a mobile phone. Set the meter display unit to power mode.
- λ Remove the handle tip and place the handle laser hole in front of the energy meter sensor head.
- λ Provides power for the system.
- λ Select the low flux range, small spot size, and set the repetition rate to 1 Hz.
- λ Puts the system in ready mode.
- λ Press the foot switch and fire a shot in the energy meter.
- λ Record the corresponding reading on the energy meter.
- λ Repeat steps 4 to 7 for the handle selectable intermediate and higher flux settings, and set the repetition rate to 4 Hz.
- λ Zheone authorized personnel will compare the recorded data to a standard energy meter and then take further steps to complete the calibration.

Notice

The distance from the energy meter sensor to the laser aperture should not exceed 10mm and should remain constant. The window surface must be parallel to the meter sensor surface.

Cautious

Work by any unauthorized person will void all warranties.

7.4 Check or replace the protection tube of the power supply

Turn off all power switches, unplug the power cord, open the fuse protector with a small screwdriver, and turn it counterclockwise. Then remove the fuse protector; replace the fuse protector only with the standard model specified by the device supplier. (Model of fuse protector: 10A/250VAC) Put in the fuse protector and jacket, and tighten the jacket clockwise. Plug the back of the device into the power cord, turn on the power switch and key switch, and test if the machine works properly.

7.5 Maintenance of cooling system

Please check regularly whether the cooling fan is working properly. If the cooling fan or cooling module does not work, the device cannot exchange heat with the outside, and the heat will accumulate inside the machine, which will cause the laser to not work properly or even damage the machine.

When the maintenance personnel test the machine, they should check the water storage capacity, water quality and cooling capacity of the water tank. If there is any abnormality, please add or change the water in time.

7.6 EMC

Table 1: Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration - electromagneticemissions</td></tr>
<tr><td colspan="3">The Intense pulsed light therapy device is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic Environment - Guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td rowspan="4">The Intense pulsed light therapy device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Intense pulsed light therapy device is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagneticimmunity			
The Intense pulsed light therapy device is intended for use in the electromagnetic environment specified below. The user of the equipment should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz repetition frequency ±1 kV for input / output lines	±2 kV for power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±0.5kV, ±1kV differential mode line-line ±0.5kV, ±1kV, ±2kV differential mode line-ground	±0.5kV, ±1kV differential mode line-line ±0.5kV, ±1kV, ±2kV differential mode line-ground	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cyclesat 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cyclesat 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: $U_T$is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The Intense pulsed light therapy device is intended for use in the electromagnetic environment specified below. The customer or the user of the Intense pulsed light therapy device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3Vrms
150kHz to
80MHz
6 Vrms
150 kHz to
80 MHz
outside ISM
bandsa</td><td>3Vrms
150kHz to
80MHz
6 Vrms
150 kHz to
80 MHz
outside ISM
bandsa</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the Intense pulsed light therapy device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 80MHz to 800MHz
$d = \left[\frac{7}{E_1}\right] \sqrt{P}$ 800MHz to 2.7GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80MHz to
2.7GHz</td><td>3V/m</td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

[a] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IPL is used exceeds the applicable RF compliance level above, the IPL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Intense pulsed light therapy device.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the Intense pulsed light therapy			
The Intense pulsed light therapy device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IPL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Intense pulsed light therapy device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	150 kHz ～ 80 MHz $d = \left\lceil \frac{3.5}{V_1} \right\rceil \sqrt{P}$	80 MHz ～ 800 MHz $d = \left\lceil \frac{3.5}{E_1} \right\rceil \sqrt{P}$	800 MHz ～ 2.5 GHz $d = \left\lceil \frac{7}{E_1} \right\rceil \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applied. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5: Recommended Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

<table>
<tr><th colspan="6">Recommended separation distances between RF wireless communications equipment</th></tr>
<tr><td colspan="6">The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><th>Frequency MHz</th><th>Maximum Power W</th><th>Distance</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>385</td><td>1.8</td><td>0.3</td><td>27</td><td>27</td><td rowspan="15">RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$E = \frac{6}{d}\sqrt{P}$
Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitter, as determinedby an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>450</td><td>2</td><td>0.3</td><td>28</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">0.2</td><td rowspan="3">0.3</td><td rowspan="3">9</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">2</td><td rowspan="3">0.3</td><td rowspan="3">28</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">2</td><td rowspan="3">0.3</td><td rowspan="3">28</td><td rowspan="3">28</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>2</td><td>0.3</td><td>28</td><td>28</td></tr>
<tr><td>5240</td><td rowspan="3">0.2</td><td rowspan="3">0.3</td><td rowspan="3">9</td><td rowspan="3">9</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
<tr><td colspan="6">Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Chapter 8 Contact Us

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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 21 CFR 807.92.

The assigned 510(k) Number: K232708

1. Date of Preparation: 11/09/2023

2. Sponsor

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4. Proposed Device Identification

Trade Name: Intense pulsed light therapy device
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Model(s): FI-L06
Regulatory Information:
Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification: II
Product Code: ONF
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Indication For Use Statement:

The Intense pulsed light therapy device is indicated for use in surgical and aesthetic applications in permanent hair removal.
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.

5. Device Description

The Intense pulsed light therapy device is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 650-1200nm. Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL Systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.

Based on this, the Intense pulsed light therapy device is indicated for use in surgical and aesthetic applications in permanent hair removal.

6. Predicate Device Identification

Predicate Device:
510(k) Number: K192519
Product Name: Multi-modality workstation
Model: AAD Dual Light
Manufacturer: Beijing Superlaser Technology Co., 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 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- AAMI/ANSI ES 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-57: 2011 Medical Electrical Equipment - Part 2-57: Particular requirements for

the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: irritation and skin sensitization
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 6-1 General Comparison

ITEM	**Proposed Device**	**Predicate Device (K192519)**	Remark
Product Code	ONF	ONF	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	SAME
Indication for Use	The Intense pulsed light therapy device is indicated for use in surgical and aesthetic applications in permanent hair removal. 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 Multi-modality workstation (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions. 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.	SAME

Table 6-2 Performance Comparison

ITEM	**Proposed Device**	**Predicate Device (K192519)**	**Remark**
Light source	Intense pulsed light (Xenon Lamp)	Intense pulsed light	Different 1
Wavelength	650-1200nm	520-650nm 800-1200nm 540-800nm 640-1200nm	SAME
Deliver system	Sapphire	Sapphire	SAME
Energy density	1-50J/cm^2	1-50 J/cm^2	SAME

Pulse Width	0.1-25ms	1-25ms	SAME
Max. Power	1500W	3500VA	Different 2
Spot size	8×40mm	Small: 40×12 mm Large: 46×16mm Ex-Large: 60×20mm	Different 3

Table 6-3 Hair removal Comparison

ITEM	Proposed Device	Predicate Device (K192519)	Remark
Wavelength Range (nm)	650—1200	640—1200	SAME
Energy Range (J/cm^2)	1-50	5-40	Different 4
Pulse Width (ms)	0.1-25	1-25	SAME
Spot Size (mm)	8×40	Small: 40×12 mm Large: 46×16mm Ex-Large: 60×20mm	Different 3

Analysis 1:

Xenon lamp is a light source output of Intense pulsed light, and the system controls the energy emitted by the xenon lamp. Intense pulsed light is emitted by the xenon lamp. As far as we know, the predicate device also uses xenon lamps to generate Intense pulsed light, so in terms of light source type, we are the same as the predicate device, and there is no difference between the two.

Analysis 2:

The proposed device is different in Max. Power from the predicate device. By complying with AAMI/ANSI/ES 60601-1 and IEC 60601-1-2, the results shown that the Max. Power of the proposed device will not raise any issues in safety and effectiveness. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 3:

The proposed device is different in Spot Size from the predicate device, Spot size only affects the area of treatment, not affect the therapeutic effect. Therefore, this difference will not affect the safety and effectiveness.

Analysis 4:

The proposed device only has slight difference in Energy Range with the predicate device. The Energy Range of the proposed device is within the allowable error range of the predicate device, which can justify that the difference in the parameter of Energy Range will not raise new safety issues of the proposed device. And the bench tests conducted on the proposed device is same with the predicate device, the results of which could support the substantially equivalency with predicate device. So the slight difference is considered to have no effect on effectiveness and safety.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K192519).