

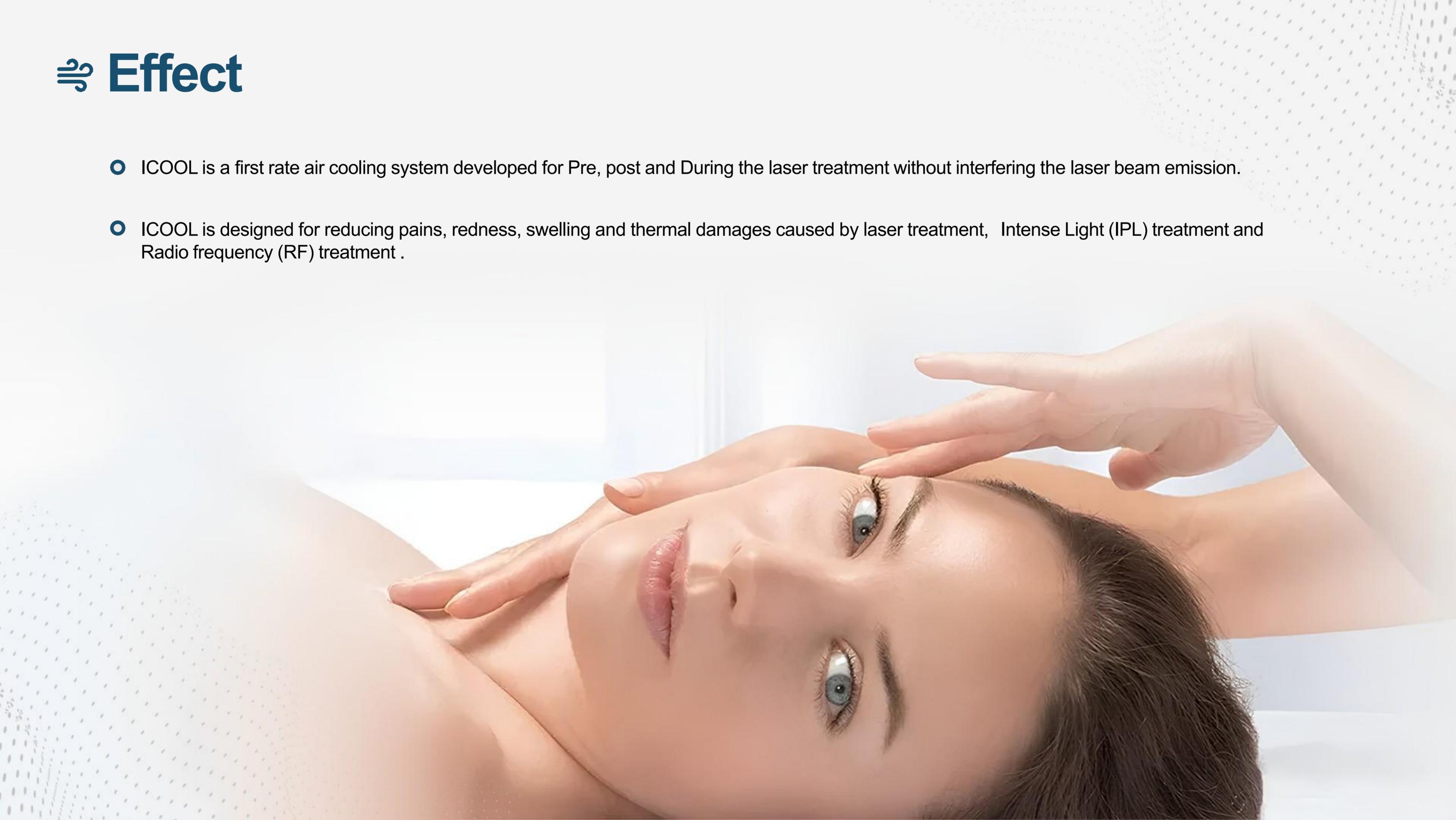
Aesthetic Skin Air cooling System

Enjoy More Comfortable
Laser Treatment



Effect

- ICOOL is a first rate air cooling system developed for Pre, post and During the laser treatment without interfering the laser beam emission.
- ICOOL is designed for reducing pains, redness, swelling and thermal damages caused by laser treatment, Intense Light (IPL) treatment and Radio frequency (RF) treatment .



Advantage

ICOOL Makes the best performances, pre, post and during the laser treatments of the following treatments

- Laser hair removal by diode laser, IPL, Long pulse Nd:yag laser or alexandrite laser.
- Radio frequency High frequency skin rejuvenation treatments.
- Temporary anesthesia before injections
- Feature of ICOOL system
- Powerful cooling air temperature (-30C)
- High power compressor makes the system work for long time continuously (Lowest temperature can keep 2 hours under 4 level fan speed)
- High speed fans makes air emitting strong for better cooling result, 6 degree cooling fan speeds for various treatment.
- Self defrosting system for best cooling performance
- Self water drainage system make safe and cleaning performance
- Fuse supporter make the procedure comfortable



Round Adapter

For reducing the skin temperature of small treatment area, such as eyebrow, underarm, forehead.



Middle Square Adapter

For reducing the skin temperature of middle square area, especially for hair removal treatment, such Arm, under. arm, leg.



Large Square Adapter

For reducing the skin temperature of large treatment area, such as thigh, belly. especially for hair removal. treatment.

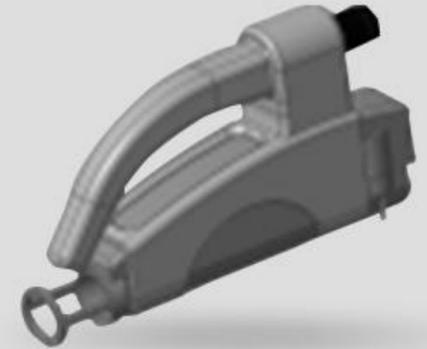
Optional Handle Connector

Adapter

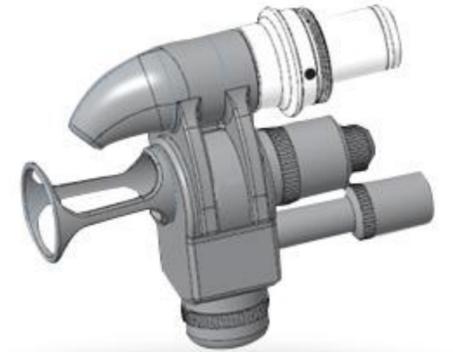
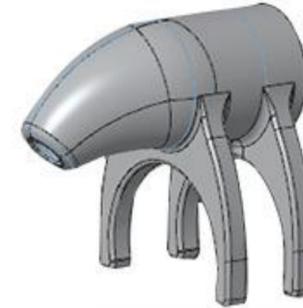
Connector

Assemble

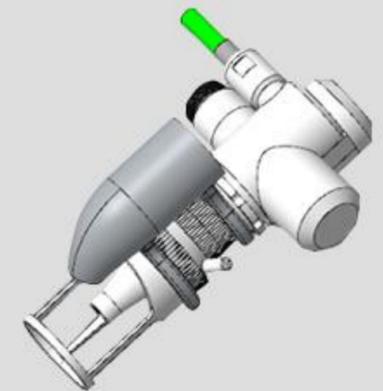
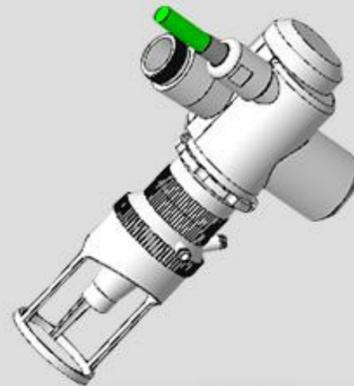
Fiber Laser



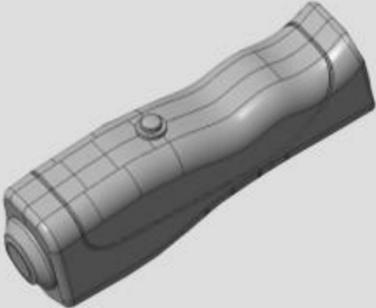
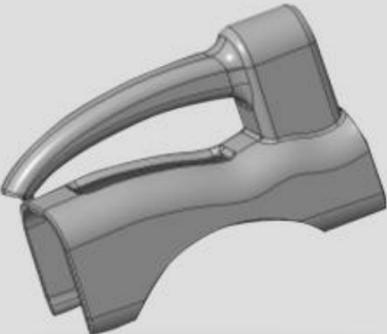
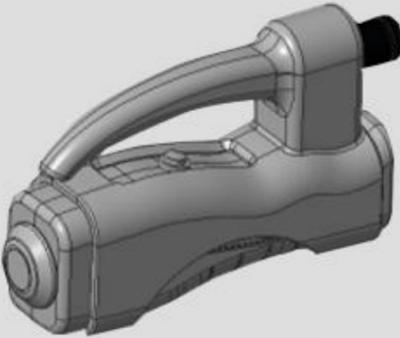
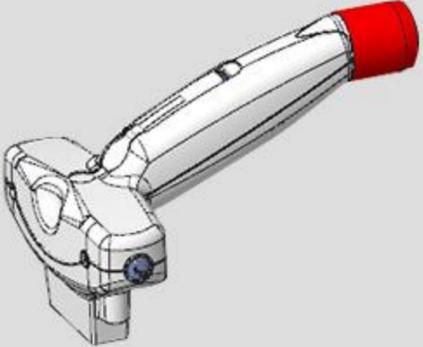
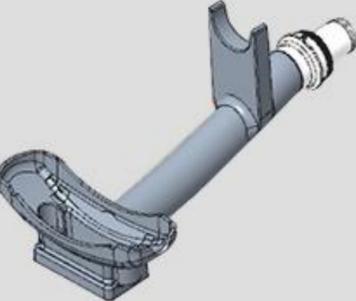
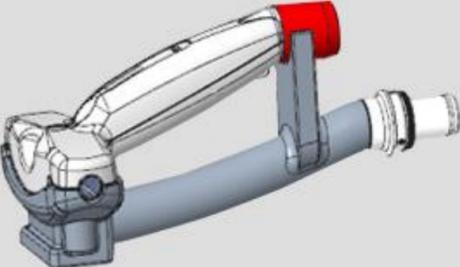
Fractional Co2 Laser



Fractional Co2 Laser



Optional Handle Connector

	Adapter	Connector	Assemble
OEM			
OEM			
OEM			

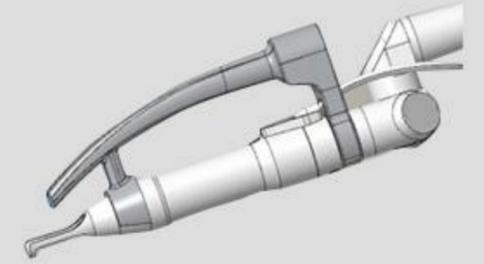
Optional Handle Connector

PICO + Long Pulse

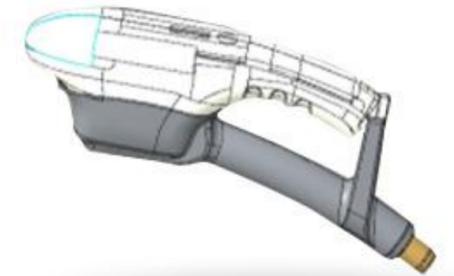
Connector



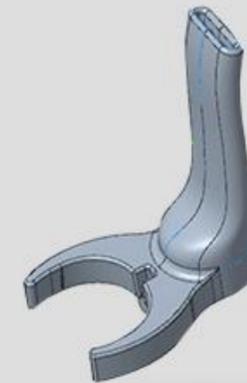
Assemble



DPL IPL SHR

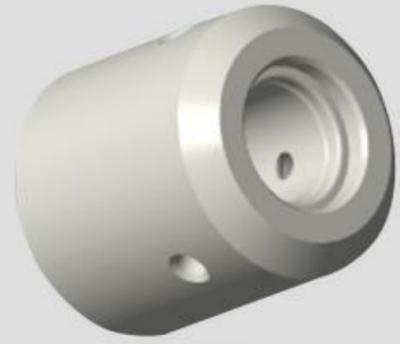


Laser Hair Removal

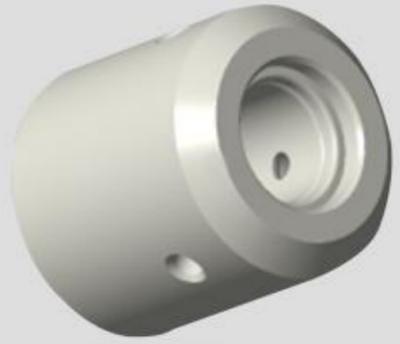


OEM

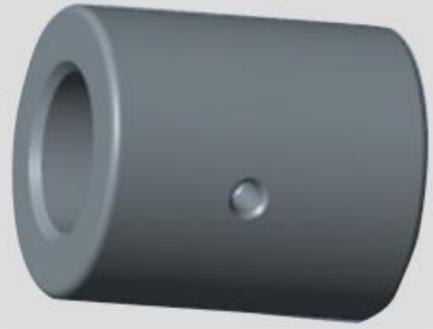
Adapter



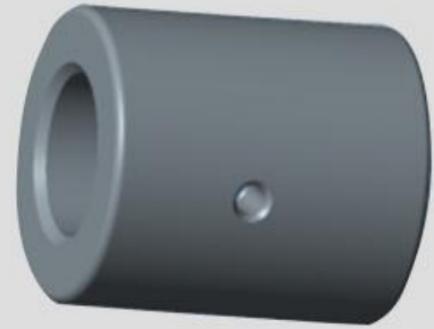
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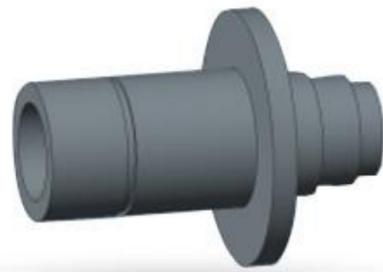


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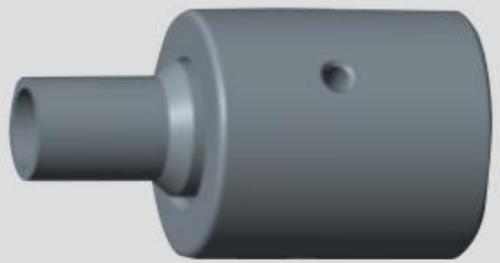
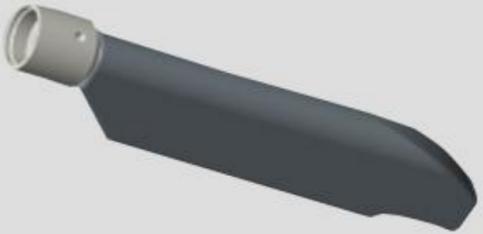


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Connector



Assemble



Certificate



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Additionally, you may contact the Division of Industry and Consumer Education (DICE) with a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/dice>) for more information or contact DICE by phone (202) 205-2000 or phone (202) 205-2000.



February 6, 2024

Beijing Sano Laser S&T Development Co., Ltd.
% Zhao Huifang
Correspondent
Microk's Business Consulting (Shanghai) Co., Ltd.
Room 1319, Block A, No 3699, Gonghexin Road
Jingnan District
Shanghai, 200040
China

Re: K233416
Trade Device Name: Cryojet Plus (SHE-ACP001-1)
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: December 26, 2023
Received: December 26, 2023

Dear Zhao Huifang:

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.access.gpo.gov/cdrh/cfdocs/cfpnm/pnm.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of device, 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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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/medical-devices/deciding-when-submit-510k-change-existing-device>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/medical-devices/deciding-when-submit-510k-change-existing-device>).

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 820.141).

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/combo-devices/guidance-regulatory-information-combination-products-reporting-combination-products>), good manufacturing practice requirements as set forth in the quality system (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 1006-1006.

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 CDRLH Learn (<https://www.fda.gov/learning-and-consultation/cdrh/learn>).

Parameter

Fuse supporter:

3 joint supporter

Power:

1500W

Temperature range:

-4°C~ -30°C/(adjustable)

Fan speed:

1~10 (adjustable)

Defrosting time:

15s

Power requirement:

110V,50hz,3A, 220V,50hz, 3A

Net weight:

62kg

Treatment Fuse:

2.5 meters

Package size:

915*515*1050mm

Dimension of system:

810*400*845mm



Machine Partner



DPL SHR IPL



Laser Hair Removal



PICO + Long Pulse



Fractional CO2 Laser

