

Has passed Medical CE, ISO13485, seriously

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español **SEARCH**

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

### 510(k) Premarket Notification

FDA Home Medical Devices Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards  
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

[New Search](#) [Back To Search Results](#)

Device Classification Name	<a href="#">Powered Laser Surgical Instrument</a>
510(K) Number	K200525
Device Name	Medical Diode Laser Hair Removal System
Applicant	Weifang Mingliang Electronics CO., LTD No.13426, Yuqing Street, High-Tech District Weifang, CN 261000
Applicant Contact	Li Mingliang
Correspondent	Beijing Believe-Med Technology Service Co., Ltd. Rm. 912, Building#15, XiYueHui, No.5, YiHe North Rd., FangShan District Beijing, CN 102401
Correspondent Contact	Ray Wang
Regulation Number	<a href="#">878.4810</a>
Classification Product Code	<a href="#">GEX</a>
Date Received	03/02/2020
Decision Date	05/27/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General & Plastic Surgery
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Page Last Updated: 06/01/2020

**40% FASTER**  
Stronger, Faster, Smarter

New 3D technology 755nm 810nm 1064nm  
Stronger 1200watt+1800watt and 40% faster



1□ Diode laser

**Stronger, Faster, Smarter, Hair removal, Reinvented**

- 2) New 3D technology 755nm 810nm 1064nm
  - 3) Stronger 1200watt+1800watt and 40% faster
  - 4) Smart 4K user friendly large screen, smart touch experience
  - 5) ICE Plus: Continuous contact cooling
  - 6) Double handles in one, more professional.
- 1200w handle for small area hair removal;**

**1800w handle for large area hair removal.**



Features of Titanium Diode laser hair removal:

- »»Safety: No skin scald, no harm to the skin and sweat glands, no scar, no any side-effect.
- »»Quick: big spot size 12\*24 mm / 12\*36 mm, effective and quick treatment on big treatment area
- »»Permanent hair removal: remove all hair on all skin types, including tanned skin.
- »»Crystal temperature:  $\sim 5-3^{\circ}\text{C}$ , reduce the painful and increase comfortable sense in treatment.



Handle features of Titanium Diode laser hair removal :

- »»USA laser bar high power 1800w
- »»TEC condenser cooling system: 2 big 1200W TEC condensers, keep the water constantly



at 24°C, ensures the machine working

continuously without stopping

»»Super Cooling effect: Sapphire Temperature-5~3°C. Effectively reduce the painful in the treatment and make

»»Italy Water Pump: more better for laser water circle, take away heat, longer life time.

»»Two water filters:two food grade exchange resin,can ensure the water quality for circulation

# Hair removal principle

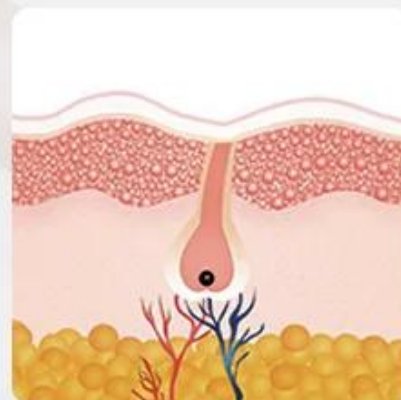
Make Your Beauty Business More Easier



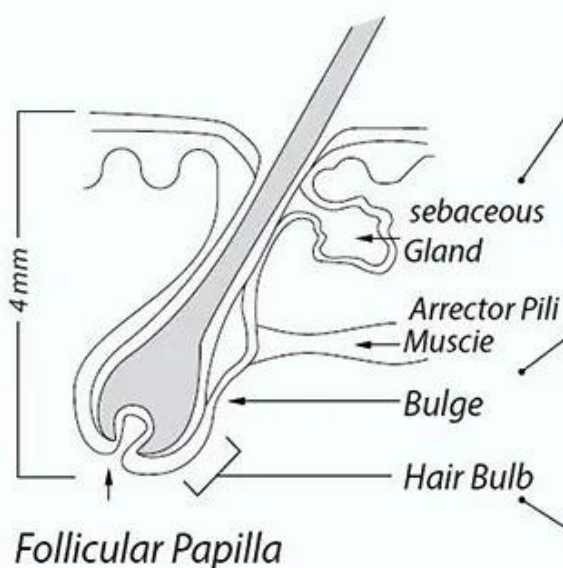
The laser selectively acts on the melanin in the hair follicle, destroying the hair-growing area



Natural hair loss, prevent regeneration, and achieve the purpose of hair removal



Hair removal also stimulates collagen regeneration, shrinks pores and makes skin firm and smooth



755nm

More powerful energy absorption by the melanin chromophore, making it ideal for the widest range of hair types and color  
- especially light-colored and thin hair

808/810nm

Deep penetration of the hair follicle with high average power with high repetition rate for fast treatment. moderate melanin absorption level making it safe for darker skin types.  
ideal for treating the arms, legs, cheeks and beard.

1064nm

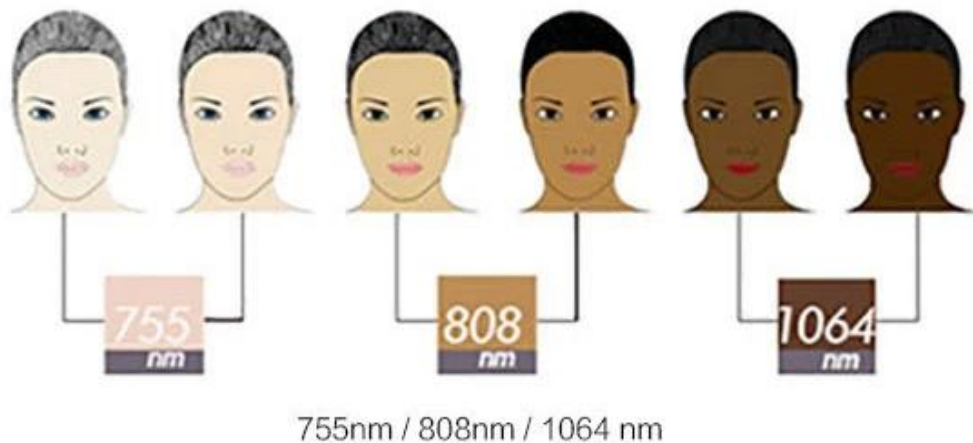
low melanin absorption, focused solution for darker skin types. Offers the deepest penetration of the hair follicle, embedded hair in areas as the scalp, armpit, and pubic area.

Suitable for diode laser hair removal on all skin of the body

Good Effect of Platinum Diode laser hair removal



For all skin types



Screen features of Platinum Diode laser hair removal

- »»Touch Screen: 14 inch easy to operate. 6 language for your choice. Logo costormization.
- »»Color for choose, also your LOGO could be put on screen and machine shell for free
- »»Metal inner structure, more stable, and suitable for long distance delivery.

The new 14-inch screen is clear  
easy to operate.



OEM/ODM SEVRICE

3D LOGO with luxurious texture.

Model	ML-808 V19 Titanium Diode laser hair removal
Laser type	755/808/1064nm
laser bar	1200w/1800w, imported from USA
Display system	14 inch true color touch screen
Laser handle shots	40 million times
Energy	10~150 j/cm2, adjustable
Pulse Duration	40~800ms adjustable
Frequency	1~10Hz
	TEC condenser
Cooling system	Air and close water circulation
	Treatment head with semiconductor
	cooling temprature adjustable
Power	3000w
Spot size	12*24mm 12*36mm
Crystal temperature	-10~3°C
Power requirement	AC220/110V, 50/60HZ