

CE Medical, ISO13485, 認證

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510(k) Premarket Notification

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Device Classification Name	Powered Laser Surgical Instrument
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	878.4810
Classification Product Code	GEX
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



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755 認證 認證 認證 認證 認證 認證 (2nm 810nm 1064nm
3) 認證 認證 40%- 認證 1800 認證 1200 認證 認證
4 認證 認證 認證 (4K 認證 認證 認證 , 認證 認證 認證
5) ICE Plus: 認證 認證 認證
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1200 認證w ; 認證 認證 認證 認證
1800 認證w 認證 認證 認證 認證.

Medical handle

As low as **350g**



12*24



12*36

2020 handle

As low as **450g**



12*20



12*35

:.....

......:.....««

.....,..... 36*12 / 24*12:.....««

......:.....««

.....,.....°C5-3~:.....««.

One minute cooling -21°C



Best **TEC Cooling** system
hair remover laser



:.....

1800««w

»».....TEC: 2 1200W TEC, ,°C24-.....

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......°C 3 ~ 5-.....:.....««

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Hair removal principle

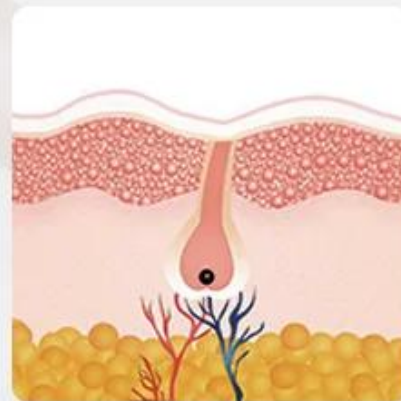
Make Your Beauty Business More Easier



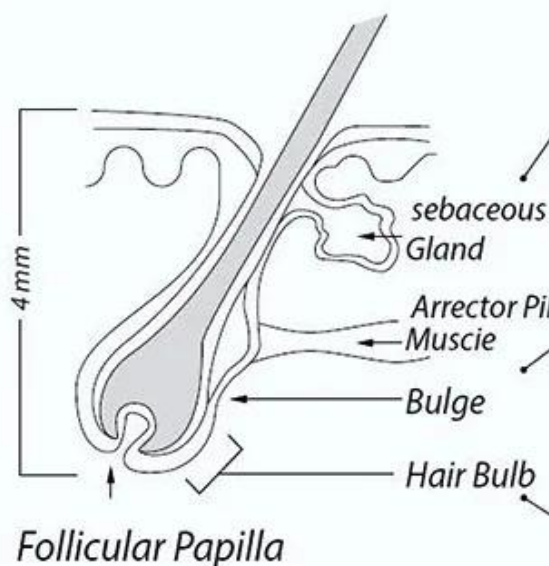
The laser selectively acts on the melanin in the hair follicle, destroying the hair-growing area



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.

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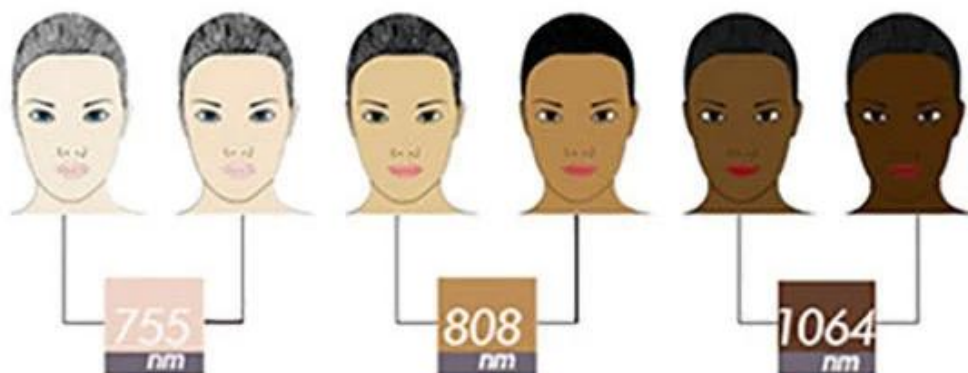


35mm

before after

Large 3.5cm spot size, and integration of three wavelengths
Hair removal is quick, efficient and convenient

For all skin types



755nm / 808nm / 1064 nm

1. The device is suitable for all skin types (Fitzpatrick I-VI).
2. The device is suitable for all skin types (Fitzpatrick I-VI).
3. The device is suitable for all skin types (Fitzpatrick I-VI).
4. The device is suitable for all skin types (Fitzpatrick I-VI).
5. The device is suitable for all skin types (Fitzpatrick I-VI).
6. The device is suitable for all skin types (Fitzpatrick I-VI).

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



OEM/ODM SEVRICE

3D LOGO with luxurious texture.

モーター	ML-808 V19 三相交流 100V 50/60Hz 三相交流 三相交流
モーター 容量	755/808/1064 W
モーター 電圧	1200w/1800w, 三相交流 三相交流
モーター 回転数	14 回転/分 三相交流 三相交流 三相交流
モーター 回転数 三相交流	40 回転/分 三相交流
モーター 三相交流	10~150 j/cm ² , 三相交流
モーター 三相	40 ~ 800ms 三相交流
モーター	1~10Hz
	三相 TEC
モーター 三相	三相交流 三相 三相交流 三相交流
	三相交流 三相交流 三相 三相交流 三相
	三相交流 三相交流 三相交流
モーター	3000 三相
モーター 三相	12*24 三相 36*12 三相
モーター 三相交流	-10~3 三相交流 三相交流
モーター 三相交流	AC220/110V, 50/60HZ