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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

1. Advanced Tech: Gold tin sintering technology,

2. Handles: Germany/USA laser bars ,10bar,1000w . 12 bar, 1200w bigger power for faster

and better hair removal, Real painless and permanent hair removal, with obvious results. Real painless and permanent hair removal, with obvious results.

3. Fast treatment: Nig spot size 10*20mm / 15*25mm / 12*38mm, frequency 1-10Hz, higher efficiency

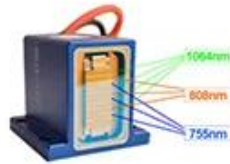
4. Continuous working :TEC condenser +air +water+ semiconductor cooling system, could actually control water temperature constant at 22~24°C, ensure machine works continuously for 24 hours without stopping, even in summer without air-conditioner.



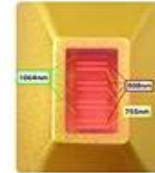
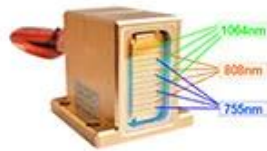
High-quality laser bars imported from Germany

1000/1200/1600ww high power

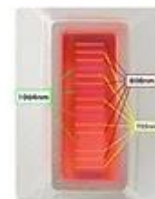
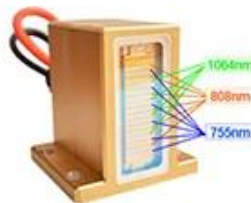
Fast hair removal



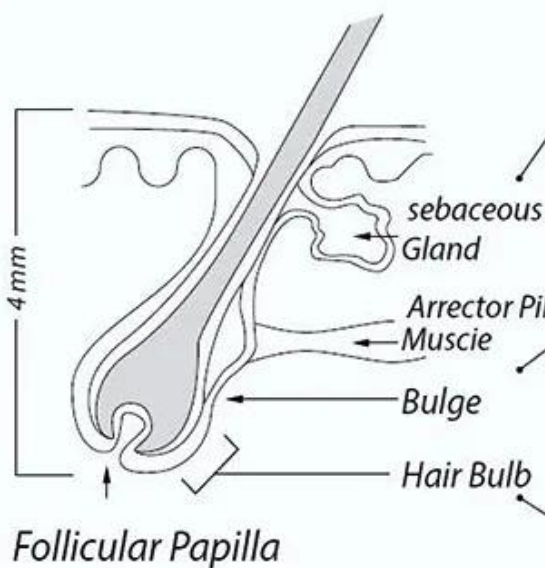
⊙ 10bar
1000W



⊙ 12bar
1200W



⊙ 16bar
1600W



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.

»»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



755nm



808nm



1064nm

