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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. Tecnologia avanzata: tecnologia di sinterizzazione dello stagno d'oro,
2. Maniglie: barre laser Germania/USA, 10bar, 1000w. 12 bar, 1200w di potenza maggiore

per una depilazione più rapida e migliore, depilazione reale indolore e permanente, con risultati evidenti. Depilazione reale indolore e permanente, con risultati evidenti.

3. Trattamento rapido: dimensioni del punto Nig10 * 20 mm / 15 * 25 mm / 12 * 38 mm, frequenza 1-10 Hz, maggiore efficienza

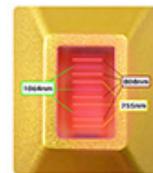
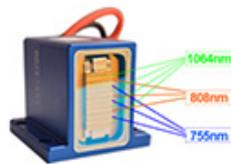
4. Funzionamento continuo: condensatore TEC aria acqua sistema di raffreddamento a semiconduttore, potrebbe effettivamente controllare la temperatura dell'acqua costante a 22~24°C, assicurarsi che la macchina funzioni ininterrottamente per 24 ore senza interruzioni, anche in estate senza condizionatore d'aria.



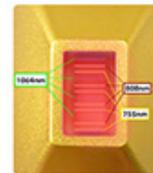
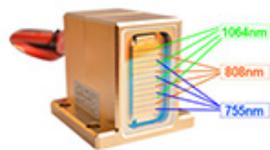
High-quality laser bars imported from Germany

1000/1200/1600ww high power

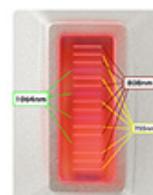
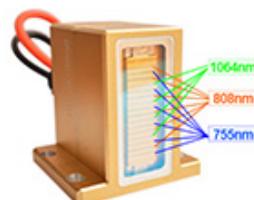
Fast hair removal



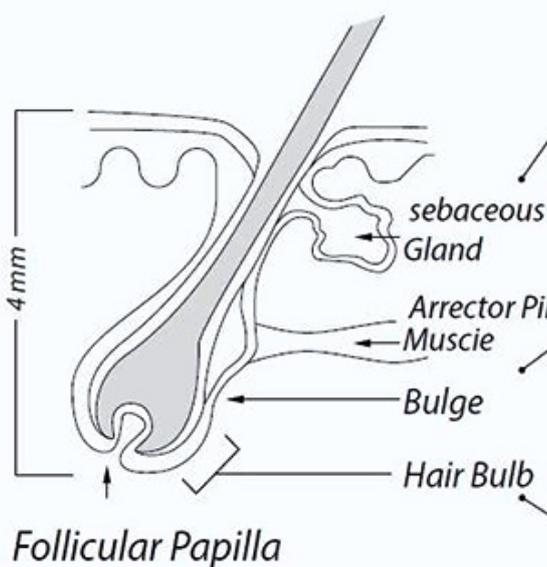
▶ 10bar
1000W



▶ 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.

»»Effetto Super Raffreddamento:

Zaffiro Temperatura-5~3°C. Riduci efficacemente il dolore nel trattamento e crea

»»Pompa dell'acqua dell'Italia:

Più meglio per il cerchio dell'acqua laser, porta via il calore, maggiore durata.

»»**Due filtri per l'acqua:**

Due resioni di scambio per uso alimentare, possono garantire la qualità dell'acqua per la circolazione



755nm



808nm



1064nm

