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## 510(k) Premarket Notification

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

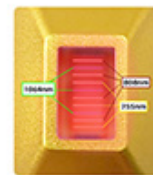
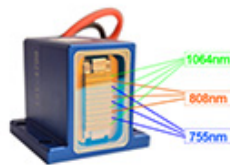
4. Funzionamento continuo: condensatore TEC aria acqua sistema di raffreddamento a semiconduttore, potrebbe effettivamente controllare la temperatura dell'acqua costante a 22~24°C, assicurarsi che la macchina funzioni ininterrottamente per 24 ore senza interruzioni, anche in estate senza condizionatore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



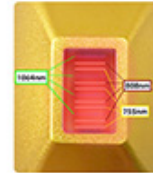
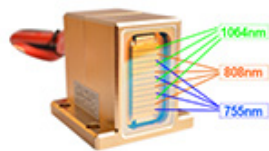
# High-quality laser bars imported from Germany

1000/1200/1600ww high power

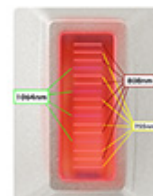
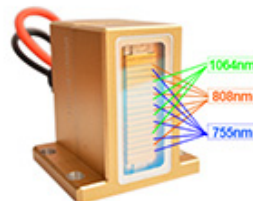
Fast hair removal



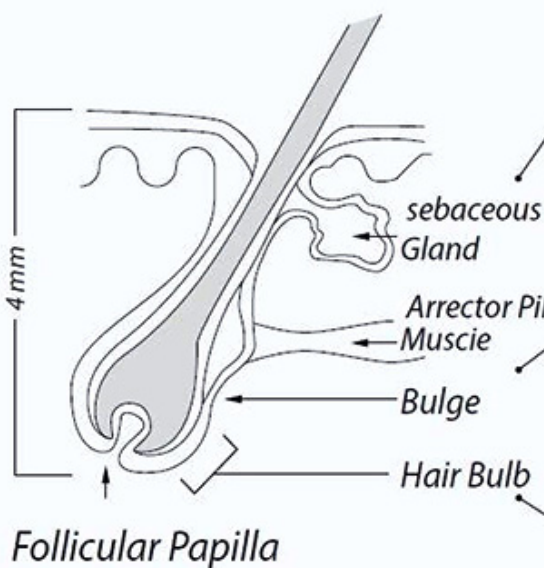
▶ 10bar  
1000W



▶ 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**

