FDA 510(k) Premarket Notification

CLEARED

K230025 IVYLASER Handhold Hair Removal Machine

Jul 3, 2023
180 days to decision

K230025 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jan 4, 2023
Decision date	Jul 3, 2023
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ivylaser (Beijing) Technology Co.,Ltd**
Location	Beijing, CN
Contact	Yuan Xiujuan
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Microkn Medical Technology Service (Shanghai) Co., Ltd.**
Contact	Heather Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230025/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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