FDA 510(k) Premarket Notification

K211922 IPL Home Use Hair Removal Device

CLEARED

Sep 20, 2021
91 days to decision

K211922 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jun 21, 2021
Decision date	Sep 20, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Beauty Every Moment Intelligent Electric Co., Ltd.**
Location	Shenzhen, CN
Contact	Luo Huajun
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Rain Yip

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/k211922/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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