FDA 510(k) Premarket Notification

CLEARED

K230122 IPL Hair Removal Device, Model(s): UI04 SD, UI04 DG

Apr 10, 2023
83 days to decision

K230122 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jan 17, 2023
Decision date	Apr 10, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Ulike Smart Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Shane Xie
510(k) history	21 submissions · 21 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Riley Chen

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