FDA 510(k) Premarket Notification

CLEARED

K232183 IPL Hair Removal Device, Model(s): T1, T2, T3, T7, T10

Sep 22, 2023
60 days to decision

K232183 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jul 24, 2023
Decision date	Sep 22, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Koli Technology Co.,Ltd**
Location	Shenzhen, CN
Contact	Qizhen Fu
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Yvonne Liu

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/k232183/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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