FDA 510(k) Premarket Notification

CLEARED

K241120 Intense pulsed light therapy apparatus (FDA01, FDA02, FDA03, FDA04S, FDA05S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA09S, FDA10S)

Jun 24, 2024
62 days to decision

K241120 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Apr 23, 2024
Decision date	Jun 24, 2024
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qiaocheng LI (Dongguan) Medical Instruments Co., Ltd.**
Location	Dongguan, CN
Contact	Quanhua Huang
510(k) history	1 submissions · 1 cleared · 2024-2024

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