FDA 510(k) Premarket Notification

K241857 LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)

CLEARED

Oct 11, 2024
106 days to decision

K241857 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241857/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Jun 27, 2024
Decision date	Oct 11, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dongguan Boyuan Intelligent Technology Co.,Ltd**
Location	Dongguan, CN
Contact	Le Li
510(k) history	4 submissions · 4 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Jilan Luo

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