FDA 510(k) Premarket Notification

CLEARED

K232932 Intense Pulse Light Therapeutic Apparatus

Dec 4, 2023
75 days to decision

K232932 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Sep 20, 2023
Decision date	Dec 4, 2023
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Greatro Electronic Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Xinhua Yue
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Bing Huang

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