FDA 510(k) Premarket Notification

K233307 Intensity Pulsed Light Therapy System

CLEARED

Mar 15, 2024
168 days to decision

K233307 · Product code: **ONF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233307/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Sep 29, 2023
Decision date	Mar 15, 2024
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Beijing Adss Development Co., Ltd.**
Location	Beijing, CN
Contact	Jijuan Wang
510(k) history	10 submissions · 10 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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