FDA 510(k) Premarket Notification

K220385 Intense Pulsed Light Equipment

CLEARED

Aug 12, 2022
183 days to decision

K220385 · Product code: **ONF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Feb 10, 2022
Decision date	Aug 12, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Globalipl Development Co., Ltd.**
Location	Beijing, CN
Contact	Jun Liu
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Ray Wang

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