

K212881 Intense Pulsed Light (IPL) SystemApr 11, 2022
213 days to decisionK212881 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Sep 10, 2021
Decision date	Apr 11, 2022
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Fansizhe Science And Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Cheng Endang
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	Jet You

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212881/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026