

K213558 IPL Hair Removal DeviceMar 8, 2022
120 days to decisionK213558 · Product code: **ONF** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Nov 8, 2021
Decision date	Mar 8, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ulike Co., Ltd.
Location	Seoul, KR
Contact	Lin Xiaoming
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Purevisionai, Inc.
Contact	Bryan Wong

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/k213558/> 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 25, 2026