

K220214 Painless IPL System - KDT750Feb 18, 2023
388 days to decisionK220214 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jan 26, 2022
Decision date	Feb 18, 2023
Days to decision	388 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Omni Laser Skinology Co., Ltd.
Location	Shanghai, CN
Contact	Avril Ouyang
510(k) history	3 submissions · 3 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	New Risen Enterprise Management Consulting Co.,Ltd
Contact	Helen Nan

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

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