

K231394 Intense Pulsed Light SystemAug 9, 2023
86 days to decisionK231394 · Product code: **ONF** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	May 15, 2023
Decision date	Aug 9, 2023
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smedtrum Medical Technology Co., Ltd.
Location	New Taipei City, TW
Contact	Crimson Wu
510(k) history	5 submissions · 5 cleared · 2022-2024

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