

K251545 Intense Pulsed Light Therapy Device (MMABM-1)Sep 4, 2025
107 days to decisionK251545 · Product code: **ONF** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251545/>**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 20, 2025
Decision date	Sep 4, 2025
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micowey Medical Equipment (Guangxi) Co., Ltd.
Location	Wuzhou, CN
Contact	Angelina Lau
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Sgs-Cstc Standards Technical Services Co., Ltd.
Contact	Iris Fung

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/k251545/> 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 13, 2026