

K250880 LED LIGHT MASK (A093)Jun 20, 2025
88 days to decisionK250880 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250880/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Mar 24, 2025
Decision date	Jun 20, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Guangyu Weilai Medical Equipment Co., Ltd.
Location	Foshan, CN
Contact	Guang Zhou
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Wenzhou Thiwe Business Consulting Co., Ltd.
Contact	Wendy Huang

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

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