

**K252189 LED Light Therapy Mask (2311, 2344, 2457, 2458)**Sep 12, 2025  
60 days to decisionK252189 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252189/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Jul 14, 2025
Decision date	Sep 12, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dongguan Yanxi Technology Co., Ltd.</b>
Location	Dongguan, CN
Contact	Xing Liang Lai
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Feiyang Drug &amp; Medical Consulting Technical Service Group</b>
Contact	Bing Huang

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252189/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026