

**K250581 KALA Red Light Face Mask (KALA-01)**May 30, 2025  
92 days to decisionK250581 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250581/>**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	Feb 27, 2025
Decision date	May 30, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Kaiyan Medical Equipment Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Alain Dijkstra
Website	<a href="https://www.kaiyanmedical.com">https://www.kaiyanmedical.com</a>
510(k) history	21 submissions · 21 cleared · 2023-2026

Shenzhen Kaiyan Medical Equipment Co., Ltd. is a medical device manufacturer based in Shenzhen, China. The company specializes in light therapy devices for clinical and aesthetic applications. Kaiyan Medical has received FDA 510(k) clearances from total submissions since 2023. All cleared devices fall within the General & Plastic Surgery category. The company maintains active regulatory status, with its most recent clearance in 2026. The company's cleared device portfolio includes LED light therapy masks, hair growth helmets, and advanced light-based aesthetic treatment s...