

**K231321 Nooance Led And Laser Helmet**Jul 31, 2023  
84 days to decisionK231321 · Product code: **OAP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k231321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	May 8, 2023
Decision date	Jul 31, 2023
Days to decision	84 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...