

**K260688 Sculpt LED Belt (HY-150A/HY-150B/HY-200A/HY-200B/  
HY-420A/HY-200D/HY-200C)**May 4, 2026  
62 days to decisionK260688 · Product code: OLI · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k260688/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	Mar 3, 2026
Decision date	May 4, 2026
Days to decision	62 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	22 submissions · 22 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...