FDA 510(k) Premarket Notification

CLEARED

K242363 HIGHERDOSE Red Light Hat (HG-120K)

Nov 20, 2024
103 days to decision

K242363 · Product code: **OAP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Aug 9, 2024
Decision date	Nov 20, 2024
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Kaiyan Medical Equipment Co., Ltd.**
Location	Shenzhen, CN
Contact	Alain Dijkstra
Website	https://www.kaiyanmedical.com
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...

REGULATORY CONSULTANT

Consulting firm	**Higherdose, LLC**
Contact	Mary Kaps

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