

K250532 Solawave 2-in-1 Skincare Mini (Model: 61043)May 22, 2025
87 days to decisionK250532 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250532/>**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 24, 2025 |
| Decision date | May 22, 2025 |
| Days to decision | 87 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...