FDA 510(k) Premarket Notification

# K253932 FACEGYM Pro Device (HD-109)

**CLEARED**

Jul 23, 2026
226 days to decision

K253932 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k253932/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO) |
| Date received | Dec 9, 2025 |
| Decision date | Jul 23, 2026 |
| Days to decision | 226 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Shenzhen Kaiyan Medical Equipment Co., Ltd.** |
| Location | Shenzhen, CN |
| Contact | Alain Dijkstra |
| Website | https://www.kaiyanmedical.com |
| 510(k) history | 24 submissions · 24 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...