CLEARED

K253400 LED Light Therapy Face Mask (FM60X, FM60X-B, FM60X-W, FM80-W, FM80, VAP1, FM100X, FM100X-B, FM100X-W)

Dec 24, 2025
85 days to decision

K253400 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253400/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Sep 30, 2025
Decision date	Dec 24, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Saidi Light Therapy Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Zaijun Hu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Candice Qui

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