

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 decisionK253400 · 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 | Feiyong 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026