

K243040 LED Light Therapy Mask (SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002, SKB-2418)Dec 20, 2024
84 days to decisionK243040 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Sep 27, 2024
Decision date	Dec 20, 2024
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Siken 3D Technology Development Co., Ltd.
Location	Shenzhen, CN
Contact	Liu Jing Quan
510(k) history	6 submissions · 6 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Feiyong Drug & Medical Consulting Technical Service Group
Contact	Huang Bing

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/k243040/> 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 13, 2026