

K252994 LED Therapy Mask (SR11CM, SR11CM1, SR11CM2, SR11CM3, SR11CM4, SR11CM5, SR11CM6, SR11CM7, SR11CM8)Dec 8, 2025
81 days to decisionK252994 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Sep 18, 2025
Decision date	Dec 8, 2025
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Ace-Tec Co., Ltd.
Location	Dongguan, CN
Contact	Fate Chen
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Feiyong Drug & Medical Consulting Technical Service Group
Contact	Tracy Che

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/k252994/>; 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