

K242908 UV Phototherapy Device (Group A: SQ308PCHFD, SQ308PCQFD, SQ308PCPFD, SQ308PCNFD, SQ308PCMFD)Dec 19, 2024
86 days to decisionK242908 · Product code: **FTC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Sep 24, 2024
Decision date	Dec 19, 2024
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	UV Phototherapy Device (Group B: SQ308PHTFF, SQ308PHSFF, SQ308PHRFF, SQ308PHZFG, SQ308PPUFF, SQ308PPVFF, SQ308PPWFG)

APPLICANT

Company	Shanghai Sigma High-Tech Co., Ltd.
Location	Shanghai, CN
Contact	Xing Guo
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Contact	He Owen

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/k242908/> 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