

K242924 OPXION Optical Skin Viewer (OPXSV1-01F)Jun 23, 2025
272 days to decisionK242924 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Sep 24, 2024
Decision date	Jun 23, 2025
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Opxion Technology, Inc.
Location	New Taipei City, TW
Contact	Shao-Hua Huang
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Ruscert Technology Co., Ltd.
Contact	Ming-Yie Jan

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

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