

K243591 OPTOVISION Endoscopic Light Source UnitFeb 19, 2025
91 days to decisionK243591 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Nov 20, 2024
Decision date	Feb 19, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Optosurgical, LLC
Location	Columbia, MD, US
Contact	Yoseph Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243591/> 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