

K242163 SmartSurgN Visualization SystemApr 20, 2026
635 days to decisionK242163 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Jul 24, 2024
Decision date	Apr 20, 2026
Days to decision	635 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smartsurgn, Inc.
Location	San Jose, CA, US
Contact	Jocelyn Long
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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