

K253181 SURGIMAGE SIM 1000H Fluorescence Imaging PlatformMay 13, 2026
229 days to decisionK253181 · Product code: **IZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 26, 2025
Decision date	May 13, 2026
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgimage Corporation
Location	Taipei City, TW
Contact	Vince Chen
510(k) history	1 submissions · 1 cleared · 2026-2026

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