

K260695 da Vinci Firefly Imaging SystemMay 22, 2026
80 days to decisionK260695 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Mar 3, 2026
Decision date	May 22, 2026
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical
Location	Sunnyvale, CA, US
Contact	Crystal Ong
Website	http://www.intuitivesurgical.com
510(k) history	17 submissions · 16 cleared · 2014-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260695/> 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 June 5, 2026