

K240852 da Vinci X Surgical System (IS4200)Jun 11, 2025
440 days to decisionK240852 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Mar 28, 2024
Decision date	Jun 11, 2025
Days to decision	440 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	da Vinci Xi Surgical System (IS4000)

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Mike Yramategui
Website	https://www.intuitive.com
510(k) history	176 submissions · 156 cleared · 1997-2026

Intuitive Surgical, Inc. is an American biotechnology company headquartered in Sunnyvale that develops and manufactures robotic surgical systems. The company specializes in minimally invasive surgery technologies, most notably the da Vinci Surgical System. Intuitive Surgical has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's dominant focus is General & Plastic Surgery devices, which represent 87% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, reflecting continued innovation and ac...

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