

**K231224 da Vinci Xi Surgical System (IS4000), da Vinci X Surgical System (IS4200)**May 12, 2023  
14 days to decisionK231224 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Apr 28, 2023
Decision date	May 12, 2023
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intuitive Surgical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Michael Prutton
Website	<a href="https://www.intuitive.com">https://www.intuitive.com</a>
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...