

K242427 da Vinci Xi Surgical System (IS4000)Apr 1, 2025
229 days to decisionK242427 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Aug 15, 2024
Decision date	Apr 1, 2025
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	da Vinci X Surgical System (IS4200)

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Jennifer Karafin
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...