

**K101581 INTUITIVE SURGICAL DA VINCI S SURGICAL SYSTEM  
WITH DA VINCI CONNECT & DA VINCI ONSITE, MODEL IS2000**Apr 8, 2011  
305 days to decisionK101581 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Jun 7, 2010
Decision date	Apr 8, 2011
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intuitive Surgical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	BRANDON HANSEN
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

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