

**K190999 SureForm 45 Curved Tip, SureForm 45 Gray Reload**Jul 12, 2019  
87 days to decisionK190999 · Product code: **NAY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k190999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Apr 16, 2019
Decision date	Jul 12, 2019
Days to decision	87 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	Nadine Nasr
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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Device record: <https://www.510kdatabase.net/k190999/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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