

**K183224 SureForm 45, SureForm 45 Reloads**Jan 18, 2019  
59 days to decisionK183224 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Nov 20, 2018
Decision date	Jan 18, 2019
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intuitive Surgical</b>
Location	Suonyvale, CA, US
Contact	Nadine Nasr
Website	<a href="http://www.intuitivesurgical.com">http://www.intuitivesurgical.com</a>
510(k) history	16 submissions · 15 cleared · 2014-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183224/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026