

K191529 da Vinci Xi Surgical System, da Vinci X Surgical SystemFeb 6, 2020
241 days to decisionK191529 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Jun 10, 2019
Decision date	Feb 6, 2020
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical
Location	Sunnyvale, CA, US
Contact	Brandon Hansen
Website	http://www.intuitivesurgical.com
510(k) history	16 submissions · 15 cleared · 2014-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191529/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026