

K242318 da Vinci SP Surgical System (SP1098)Nov 26, 2024
113 days to decisionK242318 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Aug 5, 2024
Decision date	Nov 26, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Mike Yramategui
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...

CLINICAL EVIDENCE - NCT04403022**da Vinci SP® Investigational Device Exemption Study in Colorectal Procedures**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	60 patients (actual)
Study sites	9 sites
Condition studied	Colorectal Cancer; Benign or Malignant Rectal or Colon Tumors
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 30, 2028
Sponsor	Intuitive Surgical (Industry)

Primary outcome**Performance**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04403022