

K261824 da Vinci Surgical System, Model IS5000

Jul 31, 2026
60 days to decision

K261824 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k261824/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Jun 1, 2026
Decision date	Jul 31, 2026
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Medha Sateesh Bharadwaj
Website	https://www.intuitive.com
510(k) history	178 submissions · 158 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...