

K232610 da Vinci Surgical System Model IS5000, da Vinci Insufflator and Tube Set with Smoke Evacuation

Mar 14, 2024
199 days to decision

K232610 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232610/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Aug 28, 2023
Decision date	Mar 14, 2024
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Melissa S Gonzalez
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 - NCT05682742

Clinical Investigation of the da Vinci Surgical System

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	53 patients (actual)
Study sites	4 sites
Condition studied	Thymoma; Mediastinal Tumor; Gynecologic Disease; Gynecologic Cancer; Pelvic Organ Prolapse; Prostate Disease; Prostate Cancer; Inguinal Hernia; Ventral Hernia; Obesity, Morbid
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 31, 2028
Sponsor	Intuitive Surgical (Industry)

Primary outcome

Incidence of conversion

Secondary outcome

Incidence of adverse events

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232610/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026