

**K050404 INTUITIVE SURGICAL DA VINCI SURGICAL SYSTEM
AND ENDOSCOPIC INSTRUMENTS**Apr 21, 2005
63 days to decisionK050404 · Product code: HET · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k050404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Feb 17, 2005
Decision date	Apr 21, 2005
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	MICHAEL H 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...

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