

K170879 IS4000 Stapler 45 Instrument and its Reusable Accessories, IS4000 EndoWrist Stapler 30 Instrument, IS3000 Stapler 45 Instrument and its Reusable Accessories

Sep 21, 2017
181 days to decision

K170879 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k170879/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Mar 24, 2017
Decision date	Sep 21, 2017
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Kunal Gunjal
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...