FDA 510(k) Premarket Notification

K171388 EndoWrist Stapler 45 System and Stapler 45 Reloads

CLEARED

May 31, 2017
20 days to decision

K171388 · Product code: **NAY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k171388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	May 11, 2017
Decision date	May 31, 2017
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intuitive Surgical, Inc.**
Location	Sunnyvale, CA, US
Contact	Doreen Nakamura
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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Device record: https://www.510kdatabase.net/k171388/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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