

K241638 8mm SureForm 30 Curved-Tip StaplerSep 10, 2024
95 days to decisionK241638 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Jun 7, 2024
Decision date	Sep 10, 2024
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	8mm SureForm 30 Stapler; 8mm SureForm 30 Reloads

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	Kristy Ann Darling
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...