

**K112584 5MM/8MM HARMONIC ACE(TM) CURVED SHEARS,
DISPOSABLE HARMONIC ACE(TM) INSERT, DISPOSABLE
HARMONIC(TM) CURVED SHEARS INSERT**Sep 29, 2011
23 days to decisionK112584 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k112584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Sep 6, 2011
Decision date	Sep 29, 2011
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical, Inc.
Location	Sunnyvale, CA, US
Contact	KIM T SERVANCE
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...