FDA 510(k) Premarket Notification

K071405 PROBE HOLDER SYSTEM

CLEARED

Oct 9, 2007
141 days to decision

K071405 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k071405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	May 21, 2007
Decision date	Oct 9, 2007
Days to decision	141 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...