FDA 510(k) Premarket Notification

CLEARED

K261037 780 nm SPY Portable Handheld Imaging (SPY-PHI) System

May 28, 2026
59 days to decision

K261037 · Product code: **IZI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k261037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Mar 30, 2026
Decision date	May 28, 2026
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	Mark William
Website	https://www.stryker.com
510(k) history	100 submissions · 100 cleared · 1993-2026

Stryker Endoscopy is a medical device manufacturer based in San Jose, US. The company specializes in endoscopic and surgical imaging systems for minimally invasive procedures. Stryker Endoscopy has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with its latest clearance in 2026. Its portfolio spans General & Plastic Surgery devices, orthopedic surgical tools, and obstetric and gynecologic instruments. Recent cleared devices include advanced imaging systems such as 4K camera platforms...