FDA 510(k) Premarket Notification

K982542 STRYKER URETERAL ILLUMINATOR SYSTEM III

CLEARED

Sep 22, 1998
63 days to decision

K982542 · Product code: **FCS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k982542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Catheter, Fiberoptic, Glass, Ureteral (FCS)
Date received	Jul 21, 1998
Decision date	Sep 22, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	TONY LEE
Website	https://www.stryker.com
510(k) history	101 submissions · 101 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...