

**K151243 STRYKER INFRARED ILLUMINATION SYSTEM (IRIS)
[AIM Light Source and IRIS Ureteral Kit]**Aug 20, 2015
101 days to decisionK151243 · Product code: **FCS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k151243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Catheter, Fiberoptic, Glass, Ureteral (FCS)
Date received	May 11, 2015
Decision date	Aug 20, 2015
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Endoscopy
Location	San Jose, CA, US
Contact	GOLNAZ MOEINI
Website	https://www.stryker.com
510(k) history	99 submissions · 99 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151243/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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