

K160044 Image1 SPIES SystemFeb 1, 2016
24 days to decisionK160044 · Product code: **FET** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jan 8, 2016
Decision date	Feb 1, 2016
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	SUSIE S. CHEN
510(k) history	361 submissions · 361 cleared · 1980-2024

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