

K131364 FLEXIBLE CMOS-VIDEO-CYSTO-URETHROSCOPEJan 2, 2014
234 days to decisionK131364 · Product code: **FBO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystourethroscope (FBO)
Date received	May 13, 2013
Decision date	Jan 2, 2014
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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