

K111997 IMAGE1 GI CCU MODEL 22203020-114Apr 6, 2012
268 days to decisionK111997 · Product code: **FET** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k111997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jul 13, 2011
Decision date	Apr 6, 2012
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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