

K201135 Image1 S CCU, Image1 S 4U Camera HeadSep 1, 2020
126 days to decisionK201135 · Product code: **FET** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Apr 28, 2020
Decision date	Sep 1, 2020
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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