

K193235 Telepack +Dec 20, 2019
25 days to decisionK193235 · Product code: **FET** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k193235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Nov 25, 2019
Decision date	Dec 20, 2019
Days to decision	25 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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