

K221174 Telepack +May 13, 2022
18 days to decisionK221174 · Product code: **FET** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Apr 25, 2022
Decision date	May 13, 2022
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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