

K201096 CO2mbiLEDJun 23, 2020
60 days to decisionK201096 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Apr 24, 2020
Decision date	Jun 23, 2020
Days to decision	60 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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