

K180711 FUJIFILM Endoscopic CO2 Regulator GW-100May 25, 2018
67 days to decisionK180711 · Product code: **FCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Mar 19, 2018
Decision date	May 25, 2018
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

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