

K113310 ENDOGATER AVANTAGE CO2 INSUFFLATORJun 20, 2012
225 days to decisionK113310 · Product code: **FCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k113310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Nov 8, 2011
Decision date	Jun 20, 2012
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Byrne Medical, Inc.
Location	Houston, TX, US
Contact	Brent Geiger
510(k) history	12 submissions · 12 cleared · 2003-2012

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