

**K123047 BRACCO DIAGNOSTICS INC. CO2 ENDOSCOPIC
INSUFFLATOR IN LINE TUBING SET**Aug 6, 2013
312 days to decisionK123047 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Sep 28, 2012
Decision date	Aug 6, 2013
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bracco Diagnostic, Inc.
Location	Melville, NY, US
Contact	TRACEY ALEXANDER
510(k) history	3 submissions · 3 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123047/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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