

**K111648 BRACCO DIAGNOSTICS, INC. CO2MPACT  
ENDODCOPIIC INSUFFLATOR**Nov 3, 2011  
143 days to decisionK111648 · Product code: **FCX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k111648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Jun 13, 2011
Decision date	Nov 3, 2011
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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