

K090879 INSUFLOW CO2IONSHIELDJul 23, 2009
114 days to decisionK090879 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k090879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Mar 31, 2009
Decision date	Jul 23, 2009
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lexion Medical, LLC
Location	St. Paul, MN, US
Contact	BERNARD HORWATH
510(k) history	13 submissions · 13 cleared · 2007-2019

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