

**K162332 Nexcore GI Insufflator**Sep 29, 2016  
41 days to decisionK162332 · Product code: **FCX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k162332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Aug 19, 2016
Decision date	Sep 29, 2016
Days to decision	41 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nexcore Technology, LLC</b>
Location	Winchester, MA, US
Contact	Julie Broderick
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162332/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 2, 2026