

**K161791 Aer-O-Scope Colonoscope System**Aug 11, 2016  
43 days to decisionK161791 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k161791/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jun 29, 2016
Decision date	Aug 11, 2016
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gi View , Ltd.</b>
Location	Washington, DC, US
Contact	Sharon Goldfarb
510(k) history	3 submissions · 3 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161791/> 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 May 27, 2026