

**K171673 Focus Cap**Jan 19, 2018  
227 days to decisionK171673 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k171673/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jun 6, 2017
Decision date	Jan 19, 2018
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gce Medical Corporation</b>
Location	Fresno, CA, US
Contact	Stanley Chang
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171673/> 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 31, 2026