

**K192588 G-EYE System**Apr 15, 2020  
209 days to decisionK192588 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k192588/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Sep 19, 2019
Decision date	Apr 15, 2020
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smart Medical Systems , Ltd.</b>
Location	Kfar Saba, IL
Contact	Adva Yoselzon
510(k) history	9 submissions · 9 cleared · 2006-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192588/> 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