

**K190669 Endotics**Jan 3, 2020  
294 days to decisionK190669 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190669/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Mar 15, 2019
Decision date	Jan 3, 2020
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Era Endoscopy S.R.L.</b>
Location	Peccioli, IT
Contact	Alberto Arena
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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