

**K213606 EvoEndo Single-Use Endoscopy System**Feb 14, 2022  
91 days to decisionK213606 · Product code: **FDS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k213606/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Nov 15, 2021
Decision date	Feb 14, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>EvoEndo, Inc.</b>
Location	Centennial, CO, US
Contact	Heather Underwood
510(k) history	4 submissions · 4 cleared · 2022-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Proxima Clinical Research</b>
Contact	Isabella Schmitt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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