

**K230778 EndoCore**Sep 25, 2023  
188 days to decisionK230778 · Product code: **KTI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k230778/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Mar 21, 2023
Decision date	Sep 25, 2023
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Praxis Medical, LLC</b>
Location	Tampa, FL, US
Contact	John Fisher
510(k) history	2 submissions · 2 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Praxis Medical, LLC C/O Promedic, LLC</b>
Contact	Paul Dryden

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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