

**K230769 PrevisEA Device**May 19, 2023  
60 days to decisionK230769 · Product code: **DQD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230769/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Mar 20, 2023
Decision date	May 19, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entac Medical, Inc.</b>
Location	Memphis, TN, US
Contact	Buddy Lyons
510(k) history	2 submissions · 2 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Target Health, LLC</b>
Contact	Adam Harris

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230769/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026