

**K230801 Pathfinder Endoscope Overtube with Balloon Device**Jul 28, 2023  
127 days to decisionK230801 · Product code: **FED** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Mar 23, 2023
Decision date	Jul 28, 2023
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neptune Medical, Inc.</b>
Location	Burlingame, CA, US
Contact	Alex Tilson
510(k) history	5 submissions · 4 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230801/> 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 26, 2026