

K211301 Pathfinder Endoscope OvertubeMay 28, 2021
29 days to decisionK211301 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Apr 29, 2021
Decision date	May 28, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	AlvaMed, Inc.
Contact	Ian Broome

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.netDevice record: <https://www.510kdatabase.net/k211301/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026