FDA 510(k) Premarket Notification

CLEARED

K211301 Pathfinder Endoscope Overtube

May 28, 2021
29 days to decision

K211301 · Product code: **FED** · Gastroenterology & Urology
Source: 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