FDA 510(k) Premarket Notification

K210915 Pathfinder Endoscope Cap

CLEARED

May 25, 2021
57 days to decision

K210915 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Mar 29, 2021
Decision date	May 25, 2021
Days to decision	57 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