FDA 510(k) Premarket Notification

K240853 Pathfinder® CR System

CLEARED

Jun 27, 2024
91 days to decision

K240853 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240853/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Mar 28, 2024
Decision date	Jun 27, 2024
Days to decision	91 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	Keira Jessop

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov