FDA 510(k) Premarket Notification

K230778 EndoCore

CLEARED

Sep 25, 2023
188 days to decision

K230778 · Product code: **KTI** · Anesthesiology
Source: https://www.510kdatabase.net/k230778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Mar 21, 2023
Decision date	Sep 25, 2023
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Praxis Medical, LLC**
Location	Tampa, FL, US
Contact	John Fisher
510(k) history	2 submissions · 2 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Praxis Medical, LLC C/O Promedic, LLC**
Contact	Paul Dryden

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