FDA 510(k) Premarket Notification

K200624 Percutaneous Introducer

CLEARED

Apr 27, 2020
48 days to decision

K200624 · Product code: **BSO** · Anesthesiology
Source: https://www.510kdatabase.net/k200624/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Conduction, Anesthetic (BSO)
Date received	Mar 10, 2020
Decision date	Apr 27, 2020
Days to decision	48 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Epimed International, Inc.**
Location	Johnstown, NY, US
Contact	Preston Frasier
510(k) history	14 submissions · 14 cleared · 1998-2020

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Mark Job

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