

**K200624 Percutaneous Introducer**Apr 27, 2020  
48 days to decisionK200624 · Product code: **BSO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k200624/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Mark Job

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

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