

K170671 SafeSept Transseptal GuidewireOct 20, 2017
228 days to decisionK170671 · Product code: **DRC** · Cardiovascular
Source: <https://www.510kdatabase.net/k170671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Mar 6, 2017
Decision date	Oct 20, 2017
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pressure Products Medical Device Manufacturing, LLC
Location	Morton, PA, US
Contact	Andrew Armour
510(k) history	9 submissions · 9 cleared · 2017-2026

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