

**K221707 SafeSept® Transseptal Guidewire (SS-140)**Sep 14, 2022  
93 days to decisionK221707 · Product code: **DRC** · CardiovascularSource: <https://www.510kdatabase.net/k221707/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Trocar (DRC)
Date received	Jun 13, 2022
Decision date	Sep 14, 2022
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221707/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026