

K253799 SafeSept RF Transseptal Guidewire (SSRF132)Mar 13, 2026
105 days to decisionK253799 · Product code: **DXF** · Cardiovascular
Source: <https://www.510kdatabase.net/k253799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Nov 28, 2025
Decision date	Mar 13, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SSRF132R; SSRF232; SSRF232R; SSRF135; SSRF135R; SSRF235; SSRF235R)

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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