

**K260292 HOTWIRE RF GUIDEWIRE (901XXX)**Feb 27, 2026  
29 days to decisionK260292 · Product code: **DXF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k260292/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Jan 29, 2026
Decision date	Feb 27, 2026
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HOTWIRE RF GUIDEWIRE (902XXX)

**APPLICANT**

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Company	<b>Atraverse Medical</b>
Location	Cardiff By The Sea, CA, US
Contact	Charles Yang
510(k) history	2 submissions · 2 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260292/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026