FDA 510(k) Premarket Notification

K260292 HOTWIRE RF GUIDEWIRE (901XXX)

CLEARED

Feb 27, 2026
29 days to decision

K260292 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k260292/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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