FDA 510(k) Premarket Notification

K252419 HOTWIRE RF GUIDEWIRE (901XXX)

CLEARED

Aug 27, 2025
26 days to decision

K252419 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k252419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Aug 1, 2025
Decision date	Aug 27, 2025
Days to decision	26 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HOTWIRE RF GUIDEWIRE (902XXX)

APPLICANT

Company	**Atraverse Medical, Inc.**
Location	Cardiff By The Sea, CA, US
Contact	Charles Yang
510(k) history	2 submissions · 2 cleared · 2025-2025

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