

K240900 HOTWIRE™ RF GuidewireMay 1, 2024
30 days to decisionK240900 · Product code: **DXF** · Cardiovascular
Source: <https://www.510kdatabase.net/k240900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Apr 1, 2024
Decision date	May 1, 2024
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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

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