

K241414 CrossWise RF Transseptal Access System (Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C)Sep 26, 2024
132 days to decisionK241414 · Product code: DXF · Cardiovascular
Source: <https://www.510kdatabase.net/k241414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	May 17, 2024
Decision date	Sep 26, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CrossWise RF Adapter Cable (Model CW-1002)

APPLICANT

Company	Circa Scientific, Inc.
Location	Englewood, CO, US
Contact	Jennifer Willner
510(k) history	6 submissions · 6 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	JW Regulatory Consulting, LLC
Contact	Jennifer Willner

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

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