FDA 510(k) Premarket Notification

CLEARED

K251007 CrossWise RF Transseptal Access System (Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C, CW-1085C, CW-1085V, CW-1013F)

May 1, 2025
30 days to decision

K251007 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k251007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Apr 1, 2025
Decision date	May 1, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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