

K242947 FreedomFlow™ Orbital Circumferential Atherectomy System

Nov 5, 2024
41 days to decisionK242947 · Product code: MCW · Cardiovascular
Source: <https://www.510kdatabase.net/k242947/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 25, 2024
Decision date	Nov 5, 2024
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardio Flow Inc.,
Location	Mahtomedi, MN, US
Contact	Michael Kallok
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Medical Devices Pathway, LLC
Contact	Caitlyn Dzhafarov

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242947/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026