

K250723 FreedomFlow™ Orbital Circumferential Atherectomy System (H6005/ 4Fr 3-Sphere Configuration)Apr 25, 2025
46 days to decisionK250723 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k250723/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Mar 10, 2025
Decision date	Apr 25, 2025
Days to decision	46 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

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