

# K231538 FreedomFlow Orbital Circumferential Atherectomy System

Sep 27, 2023  
120 days to decisionK231538 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231538/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 30, 2023
Decision date	Sep 27, 2023
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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