FDA 510(k) Premarket Notification

CLEARED

K233483 FreedomFlow Orbital Circumferential Atherectomy System (H6004/5Fr 3-Sphere Configuration)

Feb 15, 2024
111 days to decision

K233483 · Product code: **MCW** · Cardiovascular
Source: https://www.510kdatabase.net/k233483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Oct 27, 2023
Decision date	Feb 15, 2024
Days to decision	111 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