FDA 510(k) Premarket Notification

K242947 FreedomFlow™ Orbital Circumferential Atherectomy System

CLEARED

Nov 5, 2024
41 days to decision

K242947 · 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