September 27, 2023

Cardio Flow, Inc.
% Caitlyn Dzhafarov
Sr. Regulatory Consultant
Medical Devices Pathway, LLC.
19420 12th Ave NW
Shoreline, Washington 98177

Re: K231538
Trade/Device Name: FreedomFlow Orbital Circumferential Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 27, 2023
Received: May 30, 2023

Dear Caitlyn Dzhafarov:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.09.27 09:53:51 -04'00'

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices

OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231538

Device Name

FreedomFlow™ Orbital Circumferential Atherectomy System

Indications for Use *(Describe)*

The FreedomFlow™ Orbital Circumferential Atherectomy System is indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries. The therapy is intended for patients who are acceptable candidates for percutaneous transluminal atherectomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Cardio Flow

5.0 510(k) Summary

This 510(k) summary was prepared to provide an explanation of the basis for the determination of substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitters Name:	Cardio Flow, Inc. 3530 88th Ave NE Blaine, MN 55014
Contact Person:	Michael J. Kallok, Ph.D., FACC, FAHA; Chief Executive Officer, Director, Cardio Flow, Inc.
Contact Phone:	(800) 294-5517
Date Summary Prepared:	August 22nd, 2023
Device Trade Name:	FreedomFlow™ Orbital Circumferential Atherectomy System
Common Name:	Peripheral Atherectomy Device
Classification Name:	21 CFR 870.4875, Peripheral Atherectomy Catheter, Class II Product Code: MCW
Predicate Device:	K110389, Stealth 360™ Orbital PAD System [Diamondback 360°] Cardiovascular Systems, Inc.
Reference Device Supporting Clinical Effectiveness:	K191419, Revolution Peripheral Atherectomy System Rex Medical, L.P.

Device Description

The FreedomFlow™ Orbital Circumferential Atherectomy System is a flexible over-the-wire rotational device used to ablate atherosclerotic plaque from peripheral arterial blood vessels within the body. The FreedomFlow™ System consists of three components: User Handle with integrated driveshaft, Tubing Set, and Power Supply.

The User Handle with the integrated driveshaft is sterile, single use, and disposable. Both 5 Fr and 6 Fr variations of the User Handle are available. The User Handle provides the operator interface to control driveshaft rotation (with two speed options) and translation within the vessel. The User Handle also incorporates a guidewire mechanical clamp. The User Handle controls the saline fluid flow down the driveshaft catheter. The User Handle utilizes firmware and hardware to perform these functions. The Tubing Set is sterile, single use, and disposable. The Tubing Set connects a user provided sterile saline supply to the User Handle. The Tubing Set is connected by the operator to the User Handle. The Power Supply is a medical grade AC powered transformer, supplying DC electrical energy to the User Handle. The power supply is reusable.

Intended Use of the Device

The FreedomFlow™ Orbital Circumferential Atherectomy System is indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries. The therapy is intended for patients who are acceptable candidates for percutaneous transluminal atherectomy.

Summary of Technological Characteristics

The mechanism of operation of the FreedomFlow System is similar to other high speed rotational devices utilizing Orbital Atherectomy principles. The Atherectomy System includes multiple abrasive spheres on a rotating driveshaft. The abrasive spheres are eccentrically mounted onto the driveshaft so that when the driveshaft is rotated, the spheres move outward due to centrifugal force. These abrasive spheres are spaced along the driveshaft in a spiral configuration to optimize plaque modification through inertial forces within a vessel while still maintaining flexibility that is important in advancing through tortuous arterial anatomy. The configuration of the multiple spheres and spiral orientation are designed to optimize inertial forces at low (50 krpm) and high (76 krpm) speeds with multiple points of contact with the vessel wall during rotation, which is designed to modify plaque within the intimal luminal area and medial wall layers.

The 5 Fr variation driveshaft is compatible with a 5 Fr size introducer, the 6 Fr variation is compatible with a 6 Fr size introducer. The driveshaft of both variations has a lumen that allows translation and rotation on a 0.014" atherectomy guidewire.

Substantial Equivalence Technical Characteristics		
Feature	**FreedomFlow Orbital Circumferential Atherectomy System (Subject Device)**	**Stealth 360™ / Diamondback 360º Orbital PAD System (Predicate Device: K110389)**
Product Code, Classification	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II
Intended Use	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal.	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal.
Indications for Use	The FreedomFlow™ Orbital Circumferential Atherectomy System is indicated for use as a therapy in patients with occlusive atherosclerotic disease in peripheral arteries. The therapy is intended for patients who are acceptable candidates for percutaneous transluminal atherectomy.	The Stealth 360' Orbital PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy. The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Substantial Equivalence Technical Characteristics		
Feature	**FreedomFlow Orbital Circumferential Atherectomy System (Subject Device)**	**Stealth 360™ / Diamondback 360º Orbital PAD System (Predicate Device: K110389)**
Prescription Use Only	Yes	Yes
Single patient use, disposable	Yes	Yes
Target Body Location	Peripheral	Peripheral
Mechanism of Operation	Orbital Atherectomy	Orbital Atherectomy
	Five (5) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft to remove stenotic tissue.	One (1) diamond coated, eccentrically rotating surface (Crown) on an electric motor driven, rotating driveshaft to remove stenotic tissue.
System Components	Three (3): 1. User Handle with internal saline pump 2. Tubing Set 3. External Power supply	Three (3): 1. User Handle 2. Tubing Set 3. External saline pump with power supply
Driveshaft Variations	5 Fr and 6 Fr	4 Fr, 5 Fr, 6 Fr, 7 Fr
Driveshaft Working Length	135 cm working length for 6 Fr User Handle 150 cm working length for 5 Fr User Handle	145 cm working length
Rotational Speed	2 Speeds: 50 krpm and 76 krpm	3 Speeds: 60 krpm, 90 krpm, and 120 krpm
Saline flow rate	10 ml/minute minimum	5 ml/min to 30 ml/min
Shelf life	2 Years	2 Years
Provided sterile by Ethylene Oxide Process	Yes	Yes
Non-Pyrogenic	Yes	Yes
Sterile barrier package	Yes Tyvek lidded tray	Yes Tyvek pouched tray
Atherectomy lubricant	None	Yes
Driveshaft tracked over compatible guidewire	Yes 0.014” atherectomy guidewire	Yes 0.014” atherectomy guidewire
Software (Firmware)	Yes	Yes
Control Power Source	External Power Supply 100 to 240 VAC input	External Power Supply 100 to 240 VAC input

Non-Clinical Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalence of the FreedomFlow System, bench evaluations were conducted to confirm compliance with performance requirements.

Test	Test Method Summary			Result
The following Test and Test methods were applied to the same or equivalent methods described in the FDA Guidance: Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions, May 20, 2021:				
• Dimensional Verification • Simulated-Use Testing • Kink Resistance • Corrosion Resistance • Heat Generation	• Torsional Strength • Tensile Strength • Rotational Speed • Plaque Removal Efficiency • Particulate Evaluation	• Infusion Flow Rate • Embolization Analysis • Life Cycle/Fatigue • Orbit Testing • Coating Integrity		Pass
Usability Validation	Tested in accordance with IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability and FDA Guidance (2016): Applying Human Factors and Usability Engineering to Medical Devices and ANSI/AAMI HE75:2009 (R2018), Human Factors Engineering - Design Of Medical Devices			Pass
Biocompatibility	Evaluated and Tested to ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA Recognized Consensus Standards for: Cytotoxicity MEM Elution, (indirect material User Handle); Cytotoxicity MEM Elution; Neural Red Uptake Cytotoxicity Assay; Acute Systemic Toxicity Test; ASTM Direct Contact Hemolysis; Material Mediated Pyrogenicity Test; Intracutaneous Reactivity Test; Guinea Pig Maximization Test; Complement Activation of Direct Blood Contacting Components, SC5b-9; Partial Thromboplastin Time of Direct Blood Contacting Components; Platelet/Leukocyte Count of Direct Blood Contacting Components			Pass
Software	Software validation, verification and applicable documentation were provided in conformance to the FDA guidance documents: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and IEC 62304:2015 Medical Device Software – Software Life Cycle Processes			Pass
Electrical	Tested to 60601-1 Electrical Safety (IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) and EMC/EMI Compliance (IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1- 2: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Electromagnetic Disturbances - Requirements and Tests)			Pass
Sterility	Sterilization of the subject device was validated according to ANSI/AAMI/ISO 11135:2014, Sterilization of healthcare products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices, with a minimum sterility assurance level (SAL) of 10^{-6}.			Pass
Sterile barrier integrity	The sterile barrier package is a Tyvek lidded tray. The methods applied to evaluate the sterile barrier package integrity included post terminal sterilization simulated distribution (ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems), seal peel and bubble emission testing (ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization).			Pass
Shelf life	Confirmation of device functional performance and sterile barrier integrity (seal peel per ASTM F88 and bubble leak per ASTM F2096) with accelerated aging and simulated distribution (ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems) and bubble leak (ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization)).			Pass

Animal and cadaveric model evaluations were applied to support pre-clinical safety and effectiveness and testing included in-vivo thrombogenicity.

Clinical Performance Tests to Demonstrate Substantial Equivalency

A prospective, multi-center, single arm, open-label Clinical Study (FAST II study, NCT03635190) was conducted to evaluate the safety and effectiveness of the FreedomFlow™ System in patients with symptomatic peripheral arterial disease (PAD) of the lower extremities. The FAST II study met the pre-defined primary safety endpoint (Freedom from MAE at 30 days). The rate of freedom from major adverse events was 92.9% with a lower 95% confidence interval of 86.4%, meeting the performance goal of 85%. The study did not meet the pre-defined primary effectiveness endpoint (technical success defined as ability to achieve residual diameter stenosis less than 50% without adjunctive therapy, utilizing the core lab adjudicated data). The rate of technical success rate was 67.4% with a lower 95% confidence interval of 58.7%, missing the performance goal of 86%.

To provide a supplemental analysis of the FAST II effectiveness performance, Cardio Flow conducted a matched comparison of the FAST II FreedomFlow debulking effectiveness, as measured by post atherectomy stenosis, to real world evidence obtained from the Vascular Quality Initiative (VQI) Peripheral Vascular Intervention (PVI) registry of rotational and orbital atherectomy cases. Specifically, registry candidate patients were refined using propensity scoring to identify a control cohort of patients with well-balanced baseline covariates that included parameters relevant to atherectomy debulking. Raw data (i.e., arteriographic images) from the cohort registry and the FAST II study were randomized for blinded analysis by an independent angiographic core-laboratory. The primary study endpoint was mean Post Atherectomy Stenosis (PAS), defined as the mean residual diameter stenosis after treatment with atherectomy without adjunctive therapy. The observed PAS was 41.1% ± 19.2% for the FAST II cohort and 46.2% ± 17.1% for the PVI Registry Cohort. The FAST II PAS was demonstrated to be statistically non-inferior to the registry PAS using an alpha of 0.025 and a non-inferiority margin of 7.0% thus meeting the primary effectiveness endpoint. Therefore, the FreedomFlow Atherectomy device can be considered equivalent in performance as compared to similar, commercially-available products.

Conclusion

With respect to the subject FreedomFlow Orbital Atherectomy System, comparison to a predicate device, Diamondback 360^{o}, the Freedom Flow has the same intended use, the same technological characteristics, similar clinical and scientific data supporting substantially equivalent safety and performance outcomes as the legally marketed predicate device. The non-clinical and clinical data provide valid scientific evidence to support the conclusion that there are no different questions of safety and effectiveness raised when

compared to the predicate device. The combination of data demonstrate the FreedomFlow Orbital Atherectomy System is substantially equivalent to the predicate device.