February 15, 2024

Cardio Flow Inc.
% Caitlyn Dzhafarov
Regulatory Affairs Consultant
Medical Devices Pathway, LLC.
14330 178th Lane NE
Woodinville, Washington 98072

Re: K233483
Trade/Device Name: FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: January 18, 2024
Received: January 18, 2024

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: 2024.02.15 08:56:24 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233483

Device Name

FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)

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

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:	February 13th, 2024
Device Trade Name:	FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)
Common Name:	Peripheral Atherectomy Device
Classification Name:	21 CFR 870.4875, Peripheral Atherectomy Catheter, Class II Product Code: MCW
Predicate Device:	K231538, FreedomFlow™ Orbital Circumferential Atherectomy System Cardio Flow, Inc., **Model H6001 5Fr 5-Sphere**

Device Description

The FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere) 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. 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 (H6004 5Fr 3-Sphere) 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 modified FreedomFlow System (H6004 5Fr 3-Sphere) is the same as the predicate FreedomFlow System (H6001, 5Fr 5-Sphere cleared by K231538). 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 allowing for improved flexibility that is important in advancing through tortuous arterial anatomy. The configuration of the 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 and has a lumen that allows translation and rotation on a 0.014" atherectomy guidewire. The FreedomFlow proposed subject device (5 Fr 3-sphere configuration H6004) increases the spacing between spheres while maintaining a similar sphere treatment length by reducing the number of spheres from 5 to 3 to allow for more flexibility of the distal driveshaft as an option for user device selection while treating infrapopliteal vessels.

Table 1: Comparison to Predicate

Feature	**FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)** (Subject Device)	**FreedomFlow Orbital Circumferential Atherectomy System H6001** (Predicate Device, K231538)	**Substantial Equivalence Comments**
Product Code, Classification	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II	Same
Intended Use	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal.	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal.	Same
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	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	Same

Table 1: Comparison to Predicate			
Feature	**FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)** (Subject Device)	**FreedomFlow Orbital Circumferential Atherectomy System H6001** (Predicate Device, K231538)	**Substantial Equivalence Comments**
	patients who are acceptable candidates for percutaneous transluminal atherectomy.	patients who are acceptable candidates for percutaneous transluminal atherectomy.	
Prescription Use Only	Yes	Yes	Same
Single patient use, disposable	Yes	Yes	Same
Target Body Location	Peripheral	Peripheral	Same
Mechanism of Operation / Action (MOA)	Orbital Atherectomy Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. A diamond coated distal hypotube is attached near the tip of the driveshaft to aid driveshaft into tight lesions. .	Orbital Atherectomy Five (5) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. A diamond coated distal hypotube is attached near the tip of the driveshaft to aid driveshaft into tight lesions.	Same Same
System Components	Three (3): 1. User Handle with internal saline pump 2. Tubing Set 3. External Power supply	Three (3): 1. User Handle with internal saline pump 2. Tubing Set 3. External Power supply	Same
Driveshaft Variations	5 Fr Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft. \ A distal diamond coated hypotube aids the driveshaft into tight lesions.	5 Fr Five (5) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft. A distal diamond coated hypotube aids the driveshaft into tight lesions.	Similar The 5Fr, 3-sphere configuration (H6004) reduces the number of spheres from 5 down to 3 to allow for more flexibility of the distal driveshaft. Even with a reduction in number of spheres, the 5Fr 3-sphere configuration (H6004) has demonstrated a substantially equivalent performance to the predicate device model configuration (H6001).
Driveshaft Working Length	150 cm working length for 5 Fr User Handle	150 cm working length for 5 Fr User Handle	Same
Rotational Speed	2 Speeds:	2 Speeds:	Same

Table 1: Comparison to Predicate			
Feature	**FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere)** (Subject Device)	**FreedomFlow Orbital Circumferential Atherectomy System H6001** (Predicate Device, K231538)	**Substantial Equivalence Comments**
	50 krpm and 76 krpm	50 krpm and 76 krpm	
Display of speed in rpm on user handle	No	No	Same
Saline flow rate	10 ml/minute minimum	10 ml/minute minimum	Same
Shelf life	2 Years	2 Years	Same
Provided sterile by Ethylene Oxide Process	Yes	Yes	Same
Sterility Assurance Level (SAL)	SAL $\leq 10^{-6}$	SAL $\leq 10^{-6}$	Same
Non-Pyrogenic	Yes	Yes	Same
Sterile barrier package	Yes Tyvek lidded tray	Yes Tyvek lidded tray	Same
Atherectomy Lubricant	None	None	Same
Driveshaft tracked over compatible guidewire	Yes Commercially available 0.014" compatible guidewire	Yes Commercially available 0.014" atherectomy guidewire	Same
Guidewire Clamp	Yes	Yes	Same
User Handle traverse distance of driveshaft	12 cm	12 cm	Same
Software (Firmware)	Yes	Yes	Same
Control Power Source	External Power Supply 100 to 240 VAC input	External Power Supply 100 to 240 VAC input	Same

Summary of Testing to Support Substantial Equivalence

Table 2 below provides a summary of the testing performed to demonstrate substantial equivalence of the FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere) configuration to the predicate device, the 5 French 5-Sphere (H6001).

Performance Test	Description
Dimensional Analysis Testing	The subject device utilizes a different distal-driveshaft dimension as compared to the predicate. Dimensional analysis measurements assess diameters, lengths, angle orientation of the distal driveshaft dimensions.
Orbit Characterization Testing	Effectiveness of sanding technology as a measure of lumen diameter versus speed versus time. Maintains speed range and tolerance within simulated anatomy and characterization of orbit for subject device User Handle which includes plaque removal and removal efficiency.

Performance Test	Description
Simulated Life Test	Simulated operating life test (up to 6 minutes) of FreedomFlow System at highest speed in simulated peripheral anatomy model.
Torque Stall and Loaded Start Test	User Handle driveshaft assembly will not deform or be damaged during forced simulated torque-stalls.
Joint Tensile Test	Destructive Joint Tensile Testing.
Joint Torque Test	Destructive Joint Torque Testing.
Particulate Analysis Comparison Test	Particulate analysis testing to compare total particulate mean size and particulate counts of the subject device (5Fr 3-Sphere) and the predicate device (5Fr 5-Sphere)..
Electric System Human Cadaver Pre-Clinical Test	Formal prospective, single-center evaluation using a perfused human cadaver model to compare the debulking effectiveness and incidence of adverse events for the subject device (5Fr 3-Sphere) and predicate device (5Fr 5-Sphere) .

Conclusion

With respect to the modified FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere) the subject device has the same intended use and similar technological characteristics as the legally marketed predicate device. The design control activities summarized provide valid scientific evidence to support the conclusion that there are no different questions of safety and effectiveness raised when compared to the 5 French 5-Sphere (H6001) predicate device. The modified FreedomFlow™ Orbital Circumferential Atherectomy System (H6004 5Fr 3-Sphere) is as safe and effective as the predicate, therefore, is substantially equivalent.