November 5, 2024

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

Re: K242947
Trade/Device Name: FreedomFlow™ Orbital Circumferential Atherectomy System (H6001 & H6004)
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: September 24, 2024
Received: September 25, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.11.05 13:31:27 -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.

510(k) Number *(if known)*
K242947

Device Name
FreedomFlow™ Orbital Circumferential Atherectomy System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	October 26, 2024
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:	K231538, FreedomFlow™ Orbital Circumferential Atherectomy System Cardio Flow, Inc. & K233483, FreedomFlow Orbital Circumferential Atherectomy System (H6004/5Fr 3-Sphere Configuration)

Device Description

(H6001 & H6004)

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. 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.

Description of Change

Cardio Flow, Inc. is proposing to change the process of soldering the driveshaft to a welded process. The band-welded driveshaft is a manufacturing process change for attachment of diamond coated components to the driveshaft coil. The design of the finished driveshaft assembly is unchanged from that of the soldered version. Biocompatibility testing of this change demonstrated the new design of each configuration of the FreedomFlow™ H6001 and H6004 devices are biocompatible. There are no performances differences incurred as a result of this change.

A second change introduced in this submission is the proposed change to an interchangeable internal pump head. The design and function of the new pump is equivalent to the pump cleared under the predicate devices; there is no functional or mechanical differences in the pump design. Testing verifies all pump related specifications.

Table 1 below outlines the configurations of the FreedomFlow™ devices which are affected, and those which are unaffected, by the changes described above.

Table 1. FreedomFlow™ Device Configurations and Effect of Changes Described

Model Number	Description	Introducer Sheath Size (Fr)	Vessel Size Range	Working Length	Affected by Changes in this 510(k)
H6001	User Handle 5 Fr 5-Sphere 150 cm Length	5 French	2.0 - 4.0 mm	150 cm	Yes
H6002	User Handle 6 Fr 5-Sphere 135 cm Length	6 French	4.0 - 8.0 mm	135 cm	No
H6004	User Handle 5 Fr 3-Sphere 150 cm Length	5 French	2.0 - 4.0 mm	150 cm	Yes

Intended Use of the Device

(H6001 & H6004)

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

(H6001 & H6004)

The mechanism of operation is a type of Orbital Atherectomy. 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. 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 driveshafts are compatible with a 5 Fr size introducer and have a lumen that allows translation and rotation on a 0.014" atherectomy guidewire.

Table 2: Summary of Technological and Performance Characteristics Comparison			
Feature	**FreedomFlow Orbital Circumferential Atherectomy System** (*Subject Devices,* H6001 and H6004)	**FreedomFlow Orbital Circumferential Atherectomy System** (*Predicate Devices* H6001 [K231538] & H6004 [K233483])	**Substantial Equivalence Comments**
Product Code, Classification	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II (H6001 & H6004)	MCW, 21 CFR 870.4875 Intraluminal artery stripper, Class II (H6001 & H6004)	Same
Intended Use	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal. (H6001 & H6004)	Peripheral atherectomy: Peripheral artery luminal gain by plaque removal. (H6001 & H6004)	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 patients who are acceptable candidates for percutaneous transluminal atherectomy. (H6001 & H6004)	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. (H6001 & H6004)	Same
Prescription Use Only	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
Single patient use, disposable	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
Target Body Location	Peripheral (H6001 & H6004)	Peripheral (H6001 & H6004)	Same
Mechanism of Operation / Action	Orbital Atherectomy (H6001 & H6004)	Orbital Atherectomy (H6001 & H6004)	Same
	Five (5) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. (H6001) Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at	Five (5) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. (H6001 [K231538]) Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at	Same

	high speed to remove stenotic tissue. (H6004)	high speed to remove stenotic tissue (H6004 [K233483])	
System Components	Three (3): 1. User Handle with internal saline pump 2. Tubing Set 3. External Power supply (H6001 & H6004)	Three (3): 1. User Handle with internal saline pump 2. Tubing Set 3. External Power supply (H6001 & H6004)	Same.
Driveshaft Variations	5 Fr (H6001 & H6004)	5 Fr (H6001 & H6004)	Same *Note, the H6002 6Fr device configuration included under K231538 is not considered for this comparison.
Driveshaft Working Length	150 cm working length for 5 Fr User Handle (H6001 & H6004)	150 cm working length for 5 Fr User Handle (H6001 & H6004)	Same *Note, the H6002 6Fr device configuration included under K231538 is not considered for this comparison.
Rotational Speed	2 Speeds: 50 krpm and 76 krpm (H6001 & H6004)	2 Speeds: 50 krpm and 76 krpm (H6001 & H6004)	Same
Display of speed in rpm on user handle	No (H6001 & H6004)	No (H6001 & H6004)	Same
Saline flow rate	10 ml/minute minimum (H6001 & H6004)	10 ml/minute minimum (H6001 & H6004)	Same
Shelf life	2 Years (H6001 & H6004)	2 Years (H6001 & H6004)	Same
Provided sterile by Ethylene Oxide Process	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
Sterility Assurance Level (SAL)	SAL $\leq 10^{-6}$	SAL $\leq 10^{-6}$	Same
Non-Pyrogenic	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
Sterile barrier package	Yes Tyvek lidded tray (H6001 & H6004)	Yes Tyvek pouched tray (H6001 & H6004)	Same
Atherectomy Lubricant	None (H6001 & H6004)	None (H6001 & H6004)	Same
Driveshaft tracked over compatible guidewire	Yes Commercially available 0.014" compatible guidewire (H6001 & H6004)	Yes Commercially available 0.014" atherectomy guidewire (H6001 & H6004)	Same
Guidewire Clamp	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
User Handle traverse distance of driveshaft	12 cm (H6001 & H6004)	12 cm (H6001 & H6004)	Same
Software (Firmware)	Yes (H6001 & H6004)	Yes (H6001 & H6004)	Same
Control Power Source	External Power Supply 100 to 240 VAC input (H6001 & H6004)	External Power Supply 100 to 240 VAC input (H6001 & H6004)	Same

Conclusion

As outlined, the intended use, indications for use, and features of the FreedomFlow™ System are substantially equivalent to the predicate devices. There are no differences in substantial equivalence as a result of these incurred process changes. Cardio Flow therefore concludes that the design basis and collective data and information provided within this 510(k) demonstrate the substantial equivalence of the FreedomFlow™ device to the predicate devices.