April 25, 2025

Cardio Flow Inc.
c/o Brodie Pedersen
Regulatory Affairs Consultant
3530 88th Ave NE
Blaine, Minnesota 55014 USA

Re: K250723
Trade/Device Name: FreedomFlow™ Orbital Circumferential Atherectomy System (H6005/ 4Fr 3-Sphere Configuration)
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: April 7, 2025
Received: April 11, 2025

Dear Brodie Pedersen:

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: 2025.04.25 14:01:15 -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)*
K250723

Device Name
FreedomFlow™ Orbital Circumferential Atherectomy System (H6005/4Fr 3-Sphere Configuration)

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.**

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

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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.<br>3530 88th Ave NE<br>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: | April 24, 2025 |
| Device Trade Name: | FreedomFlow™ Orbital Circumferential Atherectomy System (H6005/ 4Fr 3-Sphere Configuration) |
| Common Name: | Peripheral Atherectomy Device |
| Classification Name: | 21 CFR 870.4875, Peripheral Atherectomy Catheter, Class II<br>Product Code: MCW |
| Predicate Device: | K242947, FreedomFlow Orbital Circumferential Atherectomy System (H6004/ 5Fr 3-Sphere Configuration) |

**Device Description**

The FreedomFlow™ Orbital Circumferential Atherectomy System is a flexible over-the-wire rotational device used to ablate atherosclerotic plaque from arterial blood vessels within the body. The FreedomFlow™ Orbital Circumferential Atherectomy System is used together with a compatible introducer sheath and 0.014-inch diameter x 300 cm (minimum length) atherectomy guidewire. The driveshaft is introduced into the patient's vasculature by traditional minimally invasive techniques. The FreedomFlow™ User Handle is available in model numbers that are listed below with vessel size ranges.

| Model Number | Description | Introducer Sheath Size (Fr) | Vessel Size Range (mm) | Working Length (cm) |
|---|---|---|---|---|
| H6001 | User Handle 5 Fr 5-Sphere 150 cm Length | 5 French | 2.0 – 4.0 mm | 150 cm |
| H6002 | User Handle 6 Fr 5-Sphere 135 cm Length | 6 French | 4.0 – 8.0 mm | 135 cm |
| H6004 | User Handle 5 Fr 3-Sphere 150 cm Length | 5 French | 2.0 – 4.0 mm | 150 cm |
| H6005 | User Handle 4 Fr 3-Sphere 150 cm Length | 4 French | 2.0 – 3.0 mm | 150 cm |

The FreedomFlow Orbital Circumferential Atherectomy System - Electric (FreedomFlow™) includes an integrated driveshaft with multiple abrasive spheres on a rotating driveshaft. The abrasive spheres are eccentrically mounted onto the driveshaft so that when the driveshaft is rotated, they move outward due to

centrifugal force. These abrasive spheres are spaced along the driveshaft in a spiral configuration to optimize plaque modification within a vessel while still maintaining flexibility for treating tortuous arterial anatomy. The User Handle includes two rotational speeds: low speed at 50,000 revolutions per minute (RPM) and high speed at 76,000 RPM.

The FreedomFlow Orbital Circumferential Atherectomy System - Electric (FreedomFlow™) is powered by Cardio Flow Power Supply H7001, which is a hospital-grade portable, reusable component. H7001 provides DC power to rotate the FreedomFlow™ driveshaft. H7001 also provides DC power to a saline pump integrated into the FreedomFlow™ User Handle. During operation the saline pump delivers saline to the distal tip of the driveshaft.

The FreedomFlow™ orbital atherectomy User Handle is supplied single patient use, sterile. The package contents include the following items.

- FreedomFlow™ orbital atherectomy User Handle with integrated electric motor and saline pump
- Saline infusion tubing set

**Note:** The nonsterile reusable power supply (H7001) is shipped separately.

**Description of Change**

Cardio Flow, Inc. is proposing the addition of a new device configuration in a 4Fr 3-Sphere to complement the existing FreedomFlow™ H6002, H6001 and H6004 driveshaft configurations. The subject device, H6005 4Fr 3-Sphere driveshaft configuration, the two component modifications from the predicate are made; sphere size and catheter tubing diameter. This allows the 4 French size variation driveshaft to be compatible with a 4 Frech Size introducer sheath. The 4Fr 3-sphere configuration (H6005) subject device utilizes a driveshaft with three diamond coated 1.25 mm diameter spheres in a spiral orientation with a diamond coated distal hypotube and a 4 French compatible catheter flush tubing for use within peripheral vessels of 2.0 to 3.0 mm in diameter.

**Indication for 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 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.

| **Table 1: Summary of Technological and Performance Characteristics Comparison** | | | |
|---|---|---|---|
| **Feature** | **FreedomFlow Orbital Circumferential Atherectomy System** *Subject Device*, H6005/4 Fr 3-Sphere | **FreedomFlow Orbital Circumferential Atherectomy System** *Predicate Device*, H6004/ 5Fr 3-Sphere (K242947/ K233483) | **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 patients who are acceptable candidates for percutaneous transluminal atherectomy. | 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. | Same |
| Prescription Use Only | Yes | Yes | Same |
| Single patient use, disposable | Yes | Yes | Same |
| Target Body Location | Peripheral vessels with 2.0- 3.0 mm diameter | Peripheral vessels with 2.0 - 4.0 mm diameter | Similar<br><br>The 4Fr 3-sphere configuration (H6005) treats vessel diameters from 2.0 to 3.0 mm in diameter, which is within the overall diameter for the predicate device. The subject device has demonstrated an equivalent performance to the |

| | | | |
|---|---|---|---|
| | | | predicate device through testing to previously established acceptance criteria. |
| Mechanism of Operation / Action | Orbital Atherectomy | Orbital Atherectomy | Same |
| | Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. | Three (3) diamond coated, eccentrically mounted, rotating surfaces (Spheres) on an electric motor driven rotating driveshaft at high speed to remove stenotic tissue. | Same |
| System Components | Three (3):<br>1. User Handle with internal saline pump<br>2. Tubing Set<br>3. External Power supply | Three (3):<br>1. User Handle with internal saline pump<br>2. Tubing Set<br>3. External Power supply | Same. |
| Driveshaft Variations | 4 Fr 3-Sphere | 5 Fr 3-Sphere | Similar<br>The 4Fr 3-sphere configuration (H6005) utilizes smaller diameter spheres (1.25 mm) as compared to the predicate device H6004 (1.50 mm). The smaller spheres allow for compatibility with 4 Fr introducer |
| Catheter Size | 4 Fr | 5 Fr | Similar<br>The 4Fr 3-sphere configuration (H6005) allows for compatibility with 4 Fr introducer |
| Driveshaft Working Length | 150 cm working length | 150 cm working length | Same |
| Rotational Speed | 2 Speeds:<br>50 krpm and 76 krpm | 2 Speeds:<br>50 krpm and 76 krpm | Same |
| 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<br>Tyvek lidded tray | Yes<br>Tyvek pouched tray | Same |
| Atherectomy Lubricant | None | None | Same |

| | | | |
|---|---|---|---|
| Driveshaft tracked over compatible guidewire | Yes<br>Commercially available 0.014" compatible guidewire | Yes<br>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<br>100 to 240 VAC input | External Power Supply<br>100 to 240 VAC input | Same |

**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.

| **Non-Clinical Test** | | | **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<br>• Simulated-Use Testing<br>• Kink Resistance<br>• Heat Generation<br>• Sterilization Adoption | • Torsional Strength<br>• Tensile Strength<br>• Rotational Speed<br>• Plaque Removal Efficiency<br>• Particulate Evaluation | • Infusion Flow Rate<br>• Life Cycle/Fatigue<br>• Orbit Testing<br>• Coating Integrity | Pass |

Other non-clinical performance tests were leveraged as unchanged portions of the FreedomFlow System. Cadaveric model evaluations were applied to support substantial equivalence of the H6005 configuration.

**Conclusion**

As outlined, the intended use, indications for use, and features of the FreedomFlow™ System H6005 / 4Fr 3-Sphere configuration are substantially equivalent to the predicate device, H6004 / 5Fr 3-Sphere configuration. There are no new questions of safety and effectiveness as a result of the minor dimensional changes in the proposed driveshaft model, as has been demonstrated through testing. 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 device.