March 18, 2022

Cardio Flow, Inc.
Michael Kallok
Chief Executive Officer
Quality & Regulatory Associates, LLC
888 East Evenuse, Mahtomedi, MN 55115 USA

Re: K213834
Trade/Device Name: Cardio Flow Peripheral Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 15, 2022
Received: February 17, 2022

Dear Michael Kallok:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Lydia Glaw
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)*
K213834

Device Name
Cardio Flow Peripheral Guidewire

Indications for Use *(Describe)*
The Cardio Flow Peripheral Guide Wire is intended for temporary placement in peripheral vasculature to facilitate the placement and exchange of diagnostic and therapeutic devices during percutaneous intravascular procedures. This guidewire device is intended for peripheral vascular use only.

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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510(k) Summary

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

Submitters Name:	Cardio Flow, Inc. 888 East Avenue Mahtomedi, MN 55115
Contact Person:	Michael J. Kallok, Ph.D., FACC, FAHA; Chief Executive Officer, Director, Cardio Flow, Inc.
Contact Phone:	(800) 294-5517
Date Summary Prepared:	December 8, 2021
Device Trade Name:	Cardio Flow Peripheral Guide Wire
Common Name:	Peripheral Guide Wire
Classification Name:	21 CFR 870.1330, Catheter Guide Wire, Class II Product Code: DQX
Predicate Device:	K103057, Asahi Astato XS 20 Guide Wire Asahi Intecc, Co. Ltd

Device Description

The Cardio Flow Peripheral Guide Wire (Guidewire), Model GW1001 is a 304V stainless steel mandrel guidewire with a fixed distal spring coil. The distal coil is radiopaque to fluoroscopy. The coil is medium-stiffness in load-force and the distal end is coated in hydrophobic silicone to facilitate tracking. The Guidewire has a maximum outer diameter of 0.36 mm (0.014-inch). The GW1001 Guidewire has overall nominal length of 325 cm.

Intended Use of the Device

The Cardio Flow Peripheral Guide Wire is intended for temporary placement in peripheral vasculature to facilitate the placement and exchange of diagnostic and therapeutic devices during percutaneous intravascular procedures. This guidewire device is intended for peripheral vascular use only.

Summary of Technological Characteristics

The following table provides a side-by-side comparison of the Guidewire to the predicate device applied to support this pre-market notification.

Substantial Equivalence Technical Characteristics			
Feature	**Cardio Flow Peripheral Guide Wire (Under Review)**	**Asahi Astato XS 20 Guide Wire (Predicate: K10357)**	**Equivalence Comments**
Product Code, Classification	DQX, 21 CFR 870.1330, Catheter Guide Wire, Class II	DQX, 21 CFR 870.1330, Catheter Guide Wire, Class II	Identical to predicate.

Substantial Equivalence Technical Characteristics			
Feature	**Cardio Flow Peripheral Guide Wire (Under Review)**	**Asahi Astato XS 40 Guide Wire (Predicate: K153443K)**	**Equivalence Comments**
Intended Use	Guidewire supporting guiding diagnostic and interventional devices through peripheral vasculature.	Guidewire supporting guiding diagnostic and interventional devices through peripheral vasculature.	Same
Indications for Use	The Cardio Flow peripheral guidewire is intended for temporary placement in peripheral vasculature to facilitate the placement and exchange of diagnostic and therapeutic devices during percutaneous intravascular procedures. This guidewire device is intended for peripheral vascular use only.	The ASAHI Astato XS 20 Peripheral Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	Same
Prescription Use Only	Yes	Yes	Same
Single use, disposable	Yes	Yes	Same
Provided sterile	Yes	Yes	Same
Sterilization method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level	$\leq 10^{-6}$	≤ 10-6	Same
Sterile barrier package	Tyvek Flexible Pouch	Tyvek Flexible Barrier	Similar
Blood contacting materials	Pt-Ni, 304V Stainless Steel Au-Sn (Solder) Silicone	Pt-Ni, 304 Stainless Steel Au-Sn and Ag-Sn (Solder) PTFE Hydrophilic coating on coil tip	Similar
Biocompatibility evaluations	Cytotoxicity ISO L929 MEM Elution, Cytotoxicity Neutral Red Uptake, ASTM Hemolysis Assay, Complement Activation Assay SC5b-9, Intracutaneous Reactivity, Sensitization Test ISO Guinea Pig Maximization, Material Mediated-Pyrogenicity, Acute Systemic Toxicity Test: Acute Systemic Injection Assay, Hemocompatibility: Heparinized Platelet and Leukocyte Count Assay, Standard In Vivo Thrombogenicity in Canine	Cytotoxicity Study, In Vitro Hemolysis Study, C3a Complement Activation Study, SC5b-9 Complement Activation Study, Intracutaneous Study, Sensitization Study, Pyrogen Study, Systemic Toxicity Study, Plasma Recalcification Time Coagulation Study, In Vivo Thromboresistance Study	Similar
Outer Diameter	0.36 mm (0.014 inches) Maximum Outer Diameter	0.36 mm (0.014 inches) Nominal Outer Diameter	Similar
Overall Length	325 cm	180 to 300 cm	Similar
Tip Length	35 mm	17 cm	Similar
Tip Flexibility (Tip Load)	10 to 25 gf (13 gf average)	20 gf	Similar
Shelf life	2 Years	3 Years	Similar

Non-clinical Performance Tests to Demonstrate Substantial Equivalency
To establish the technical equivalency of the Guidewire, bench evaluations were conducted to confirm compliance with performance requirements.

Test	Test Method Summary	Result
Corrosion Resistance Dimensional Verification Kink Resistance Lubricity Particulate Evaluation Radiopacity Silicone Coating Integrity Simulated Use (Compatibility) Tensile Strength Tip Flexibility Tip Pull Torque Strength Torqueability (Torque Response)	FDA Guidance: Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling, (October 10, 2019)	Pass
Flex Resistance	The guidewire will be resistant to damage by flexing in accordance to ISO 11070:2014 Annex G criterion, between two cylindrical mandrels with diameters equal to 20 times the guide wire diameter.	Pass
Fracture Resistance	The guide wire shall not fracture or fail when tested in accordance to ISO 11070:2014 Annex F criterion, test article wrapped around a mandrel with a diameter 10 times larger than the guidewire outside diameter.	Pass
Tip Load	Guidewire tip load buckling force inducing buckling deformation with a 20 mm gauge length from the distal tip is documented.	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 assumed level (SAL) of 10^{-6}.	Pass
Sterile barrier integrity	The sterile barrier package is a flexible pouch. The methods applied to evaluate the sterile barrier package integrity included post terminal sterilization simulated distribution, seal peel and bubble emission testing.	Pass
Biocompatibility	ISO 10993-4, -5, -10, -11 appliable standard applied for: Cytotoxicity, Complement Activation, Intracutaneous Reactivity, Sensitization, Material Mediated-Pyrogenicity, Acute Systemic Toxicity, and Standard in Vivo Thrombogenicity in Canine. ASTM F756 applied for Hemolysis. ASTM F2888 applied for Heparinized Platelet and Leukocyte Count.	Pass
Shelf life two (2) years	Confirmation of device functional performance and sterile barrier pouch integrity (seal peel per ASTM F88 and bubble leak per ASTM F2096) with accelerated aging and simulated distribution per ASTM 4169-16 and bubble leak (ASTM F2096).	Pass

Animal and Clinical data are not needed to support substantial equivalence.

Conclusion
The Guidewire meets performance requirements equivalent to the predicate device. The intended use and technology of the Guidewire is the same as the predicate device.