October 24, 2025

Coroventis Research AB
Johan Svanerud, CEO
Ulls väg 29A
Uppsala, 75651
Sweden

Re: K252238
Trade/Device Name: CoroFlow Cardiovascular System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, OUG
Dated: July 17, 2025
Received: September 24, 2025

Dear Johan Svanerud:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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)*

K252238

Device Name

CoroFlow Cardiovascular System

Indications for Use *(Describe)*

CoroFlow is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.

CoroFlow is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from one or more measuring devices.

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.

510(k) #: K252238

510(k) Summary

Prepared on: 2025-10-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Coroventis Research AB
Applicant Address	Ulls väg 29A Uppsala 75651 Sweden
Applicant Contact Telephone	+4670-970 31 00
Applicant Contact	Mr. Johan Svanerud
Applicant Contact Email	jsvanerud@coroventis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CoroFlow Cardiovascular System (12000ww)
Common Name	Programmable diagnostic computer
Classification Name	Computer, Diagnostic, Programmable
Regulation Number	870.1425
Product Code(s)	DQK, OUG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201881	CoroFlow Cardiovascular System	DQK
K183099	Quantien Measurement System	DQK
K092105	RadiAnalyzer Xpress	DQK

Device Description Summary

21 CFR 807.92(a)(4)

CoroFlow Cardiovascular system is used to calculate, display and store physiological parameters based on pressure and temperature measurements from Abbott Medical's PressureWire and Wi-box.
Calculated parameters include physiological indices to assess coronary lesion severity (FFR, Pd/Pa, RFR) and indices to assess coronary micro-circulation (IMR, CFR).

The system also provides indices based on the same raw pressure and temperature measurements (IMR_Corr, RRR, Absolute Flow/ Resistance, dP/dt, Tau).

CoroFlow is installed on a personal computer and receives measurement data wirelessly via the CoroHub Receiver. Information is displayed on the computer screen which can optionally be slaved to a monitor inside the coronary cathlab. Data can be stored on a local storage unit or transferred to a network location.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

CoroFlow is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.

CoroFlow is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various

physiological parameters based on the output from one or more measuring devices.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are identical compared to the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

CoroFlow™ Cardiovascular System 3.7 is considered substantially equivalent to the currently marketed primary predicate device (CoroFlow™ Cardiovascular System 3.01, K201881 and the secondary predicate device QUANTIEN™ Measurement System, K183099, based on comparisons of the device classifications, technological characteristics, intended use and indications for use.
CoroFlow™ Cardiovascular System 3.7 receives pre-conditioned digital measurement data from the same sensors, utilizing the exact same radio technology for measurement data transmission, as the predicate devices. The CoroFlow 3.7 system provides the same calculated indices as the primary predicate device, with addition of PPG. Existing indices use the same algorithms with equivalent results as demonstrated in comparative performance testing.
The subject device presents the same indices as the primary predicate device, with addition of PPG, and the indices are based on the same measurement data as for the predicate devices, collected in the same clinical context and in the same clinical procedure, the subject device has essentially the same technological characteristics as the predicate devices in relation to software features/presented indices. The TouchPad optional accessory introduced with the subject device is intended to be used in the patient environment, although not with patient contact, different compared to the primary predicate device, but similar to the secondary predicate device.
Coroventis design control, verification testing and usability validation have demonstrated that the subject device is safe and effective and do not raise different questions of safety and effectiveness compared to the predicate devices.

The CoroFlow Cardiovascular System 3.7 provides the user with additional clinical information (PPG) and improves the clinical use of the system while not changing the intended use, introducing new device hazards or alter the fundamental scientific technology of the device as compared to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification and Validation testing were completed to demonstrate safety and effectiveness and ensure that the subject device performs as intended. Design verification and validation included the following:
- Verification – performed to ensure that the subject device meets specified system requirements and functions as intended.
- Validation/Usability Engineering – performed to ensure that the subject device meets user requirements and to identify, evaluate and eliminate or reduce use errors.

The following standards were applied:
- ISO 14971:2019
- IEC 62304 Ed.1.1
- IEC 82304-1 Ed. 1.0
- IEC 81001-5-1 Ed. 1.0
- ISO 15223-1 Ed. 4
- IEC 62366-1 Ed .1.1 / IEC 60601-1-6 Ed. 3.2
- IEC 60601-1 Ed. 3.2
- IEC 60601-1-2 Ed. Ed. 4.1
- ASTM D4169-23
- IEC TS 60601-4-2 Ed. 1.0

No clinical study was performed as a part of either the product development or in support of the substantial equivalence of CoroFlow as the intended use/indications for use and technological characteristics are equivalent to the predicate devices.
However, the safety and effectiveness of CoroFlow and the PPG index introduced in CoroFlow 3.7 was demonstrated. The performed clinical evaluation showed a valid clinical association, analytical validation and clinical validation.

The performed bench testing and evaluation of clinical reference data confirms that CoroFlow Cardiovascular System 3.7 (including CoroFlow TouchPad) is as safe and effective and performs as well as the legally marketed predicate devices.