November 13, 2020

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

Re: K201881
Trade/Device Name: CoroFlow Cardiovascular System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 2, 2020
Received: November 5, 2020

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 (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,

for

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201881

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.

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

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510(k) Summary
Per 21 CFR §807.92

510(k) number:	K201881
Date prepared:	24 September 2020
Submitter name:	Coroventis Research AB
Submitter address:	Ulls väg 29A SE-756 51 Uppsala Sweden
Name of official correspondent / Contact person:	Johan Svanerud, CEO Phone: +46 70-970 31 00 Fax: - Email: jsvanerund@coroventis.se
Proprietary/Trade Name:	CoroFlow™ Cardiovascular system
Common/Usual name:	CoroFlow™
Device classification code:	DQK (Programmable Diagnostic Computer)
Regulation number and name:	21 CFR 870.1425, Programmable diagnostic computer
Device classification:	II
Predicate device(s):	Primary: QUANTIEN™ Measurement System (K183099) with Software Version 1.12.1, cleared 28 February 2019. Secondary: RadiAnalyzer® Xpress (K092105) with accessory software RadiView® and Physiomon™, cleared 9 October 2009.
Device description:	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).

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<table>
<tr><td></td><td>The system also provides novel 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.</td></tr>
<tr><td>Indications for Use/ Intended Use:</td><td>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.</td></tr>
<tr><td>Contraindication(s):</td><td>The system has no patient alarm functions. Do not use for cardiac/vital signs monitoring.</td></tr>
<tr><td>Patient category/population:</td><td>CoroFlow™ is intended to be used with adult patients with cardiovascular diseases</td></tr>
<tr><td>Comparison of subject device to predicate devices</td><td>
<table>
<tr><th>Feature/ Characteristic</th><th>QUANTIEN™ (Predicate Device) K183099</th><th>CoroFlow™ (Subject Device) K201881</th></tr>
<tr><td>Intended use / Indications for use statements</td><td>The QUANTIEN™ system 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 electrodes, transducers or measuring devices.

The QUANTIEN Measurement System is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease.</td><td>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.

CoroFlow™ is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.</td></tr>
<tr><td colspan="3">The intended use/indications for use statements of the subject device is identical to the predicate device. Except that the predicate device specifically identifies electrodes, transducers as input data sources and specifically identifies coronary or peripheral artery disease. However, the general purpose of the subject device is the same as the for the predicate device.</td></tr>
</table>
</td></tr>
</table>

	Design principle	Plastic enclosure with screen display. Modular processing and input hardware modules for input and output signals. Including Radio Receiving capabilities for wireless reception of digital data from measurement devices	Software to be installed on a stand-alone standard Windows PC. USB Radio Receiving device for wireless reception of digital data from measurement devices.
		Subject device is a software while predicate device has dedicated hardware. CoroFlow is installed on a stand-alone standard Windows PC outside the patient environment.	
	Operating principle	Pressure and temperature measurement data received from Abbott PressureWire and Aortic pressure transducer (through Wi-Box). Parameters calculated and displayed on a screen.	Pressure and temperature measurement data received from Abbott PressureWire and Aortic pressure transducer (through Wi-Box). Parameters calculated and displayed on a screen.
		Identical	
	Signal input	Wireless and /or cable data input from Abbott PressureWire Certus, Aeris, X Wireless (aortic pressure) data input from external pressure transducer via Abbott Wi-Box. Cable (aortic pressure) data input from Catlab recording system	Wireless data input from Abbott PressureWire Aeris, X Wireless (aortic pressure) data input from external pressure transducer via Abbott Wi-Box.
		The signal input for the subject device is identical compared to the predicate device, except that the predicate device can receive input via physical cables.	
	Signal performance specifications	**Pressure** Range: 30 to +300mmHg Accuracy: ± 1 mmHg plus ± 1% of readings (over the pressure range – 30 to 50mmHg), ± 3% of reading (over the range 50 to 300mmHg) Frequency response: 0 – 25Hz **Temperature** Range: 15 - 42ºC Accuracy: 0.05ºC or 10% ΔT whichever greatest	**Pressure** Range: 30 to +300mmHg Accuracy: ± 1 mmHg plus ± 1% of readings (over the pressure range – 30 to 50mmHg), ± 3% of reading (over the range 50 to 300mmHg) Frequency response: 0 – 25Hz **Temperature** Range: 15 - 42ºC Accuracy: 0.05ºC or 10% ΔT whichever greatest
		Identical	
	Wireless data communication	- 2.4 GHz point to point radio communication. - FHSS frequency hopping	- 2.4 GHz point to point radio communication. - FHSS frequency hopping

		spread spectrum protocol - Checksum controlled	spread spectrum protocol - Checksum controlled
		Identical	
	Calculated indices - FFR	Yes	Yes
	Calculated indices - Pd/Pa	Yes	Yes
	Calculated indices - CFR	Yes	Yes
	Calculated indices – IMR	No (Refer to secondary predicate device)	Yes
	Calculated indices – IMR_Corr	No	Yes
		See clinical testing section below.	
	Calculated indices – Absolute Flow	No	Yes
		See clinical testing section below.	
	Calculated indices – RFR	Yes	Yes
	Calculated indices – RRR	No	Yes
		See clinical testing section below.	
	Calculated indices – PB-CFR	No	Yes
		See clinical testing section below.	
	Calculated indices – dP/dt	No (Refer to secondary predicate device)	Yes
	Calculated indices – Tau	No	Yes
		See clinical testing section below.	

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Feature/ Characteristic	RadiAnalyzer® Xpress (Predicate Device) K092105	CoroFlow™ (Subject Device) K201881
Intended use / Indications for use statements	RadiAnalyzer® Xpress 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 electrodes, transducers or measuring devices. RadiAnalyzer® Xpress is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire.	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. CoroFlow™ is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.
	The intended use/indications for use statements of the subject device is identical to the predicate device. Except that the predicate device specifically identifies electrodes, transducers as input data sources and specifically identifies patients that undergo measurement of physiological parameters with PressureWire. The general purpose of the subject device is the same as the for the predicate device.	
Design principle	Plastic enclosure with screen display. Modular processing and input hardware modules for input and output signals. Including Radio Receiving capabilities for wireless reception of digital data from measurement devices	Software to be installed on a stand-alone standard Windows PC. USB Radio Receiving device for wireless reception of digital data from measurement devices.
	Subject device is a software while predicate device has dedicated hardware. CoroFlow is installed on a stand-alone standard Windows PC outside the patient environment.	
Operating principle	Pressure and temperature measurement data received from Abbott PressureWire and Aortic pressure transducer.	Pressure and temperature measurement data received from Abbott PressureWire and Aortic pressure transducer (through Wi-Box). Parameters calculated and displayed on a screen.
	Identical, except that the predicate device receives data via cable connection and the subject device receives data via wireless links.	
Signal input	Cable connection data input from Abbott PressureWire Certus Cable connection (aortic pressure)	Wireless data input from Abbott PressureWire Aeris, X Wireless (aortic pressure) data input

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		data input from external pressure transducer.	from external pressure transducer via Abbott Wi-Box.
		Input from same PressureWire Sensor (K972793), except that the predicate device receives data via cable connection and the subject device receives data via wireless links.	
	Signal performance specifications	**Pressure** Range: 30 to +300mmHg Accuracy: ± 1 mmHg plus ± 1% of readings (over the pressure range – 30 to 50mmHg), ± 3% of reading (over the range 50 to 300mmHg) Frequency response: 0 – 25Hz **Temperature** Range: 15 - 42ºC Accuracy: 0.05ºC or 10% ΔT whichever greatest	**Pressure** Range: 30 to +300mmHg Accuracy: ± 1 mmHg plus ± 1% of readings (over the pressure range – 30 to 50mmHg), ± 3% of reading (over the range 50 to 300mmHg) Frequency response: 0 – 25Hz **Temperature** Range: 15 - 42ºC Accuracy: 0.05ºC or 10% ΔT whichever greatest
		Identical	
	Wireless data communication	NA	- 2.4 GHz point to point radio communication. - FHSS frequency hopping spread spectrum protocol - Checksum controlled
		Predicate device receives data exclusively via cable connection.	
	Calculated indices - FFR	Yes	Yes
	Calculated indices - Pd/Pa	Yes	Yes
	Calculated indices - CFR	Yes	Yes
	Calculated indices – IMR	Yes	Yes
	Calculated indices – IMR_Corr	No	Yes
		See clinical testing section below.	
	Calculated indices – Absolute Flow	No	Yes
		See clinical testing section below.	
	Calculated indices – RFR	No (refer to primary predicate device)	Yes
	Calculated indices – RRR	No	Yes
		See clinical testing section below.	
	Calculated indices – PB-CFR	No	Yes
		See clinical testing section below.	
	Calculated indices – dP/dt	Yes	Yes
	Calculated indices – Tau	No	Yes
		See clinical testing section below.	

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Non-clinical testing	Verification and Validation testing were completed to demonstrate substantial equivalence 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. The software was validated in accordance with IEC 62304:2015. - Validation/Usability Engineering – performed to ensure that the subject device meets user requirements and to identify, evaluate and eliminate or reduce use errors.
Applied standards	- IEC 62304:2015 - IEC 82304-1:2016 - EN ISO 15223-1:2016 - EN ISO 14971:2012 - IEC 62366:2015 - IEC 60601-1-1:2006/AMD1:2012 - EN 60601-1-2:2014 - IEC 60950-1:2005 - CISPR11:2009 - SS-EN 55302:2015 - FCC Part 15B - IEC 60529:2013 - EN 300 328 V2.1.1:2017 - AAMI TIR 69:2017 - ANSI C63.27:2017 - ASTM D4169-16
Clinical testing	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 substantial equivalence of CoroFlow and the indices it calculates was demonstrated as per FDA guidance document Medical Device (SAMD): Clinical Evaluation issued on Dec 8, 2017). As per the guidance, the performed clinical evaluation showed a valid clinical association, analytical validation and clinical validation of the SaMD.

Conclusion on substantial equivalence

The CoroFlow™ Cardiovascular system is equivalent to QUANTIEN™ Measurement System (K183099) in terms of intended use and the non-clinical data support substantial equivalence in terms of technological and performance characteristics. The verification, validation and usability activities demonstrate that CoroFlow™ is substantially equivalent to the predicate device.