July 17, 2024

ACIST Medical Systems, Inc
Bobbie Daughters
Senior Regulatory Affairs Specialist
7905 Fuller Rd
Eden Prairie, Minnesota 55344

Re: K233904
Trade/Device Name: ACIST RXi System; ACIST Navvus II Catheter
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: December 11, 2023
Received: December 11, 2023

Dear Bobbie Daughters:

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.

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,

Robert T. Kazmierski -S

for

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.

510(k) Number *(if known)*
K233904

Device Name
ACIST RXi System and Navvus II MicroCatheter

Indications for Use *(Describe)*
The ACIST RXi System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus II MicroCatheter is intended for use with the ACIST RXi System.

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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K233904 - 510(k) Summary [21 CFR 807.92]

SUBMITTER

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Date Prepared: 11 December 2023

DEVICE

Name of Device: RXi® System and Navvus®II MicroCatheter
Common or Usual Name: Catheter tip pressure transducer
Classification Name: Transducer, pressure, catheter tip (870.2870)
Regulatory Class: II
Product Code: DXO

PREDICATE DEVICE

ACIST RXi® System and Navvus®II MicroCatheter (K190473)

REFERENCE DEVICE

The dPR index calculation algorithm software upgrade subject to this submission is substantially equivalent to the reference device, Volcano iFR Modality in the s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System cleared under K173860 on 04/11/2018 for similar intended use.

DEVICE DESCRIPTION

The current RXi system obtains intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The RXi measures intravascular pressure in a hyperemic state following administration of adenosine as fractional flow reserve (FFR). The proposed software update for the RXi system adds a diastolic pressure ratio (dPR), which measures intravascular pressure in a non-hyperemic (resting) state. Both current and proposed ACIST RXi Systems are used in conjunction with the Navvus Catheter.

The proposed RXi System consists of a console containing embedded software that provides the main user interface. The system is used with the Navvus catheter which contains a pressure sensor for acquisition of

pressure distal (Pd) to a lesion. The proximal aortic pressure (Pa) is acquired via an interface to a third-party hemodynamic system. The system is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display fractional flow reserve (FFR) using hyperemic agents and/or non-hyperemic indices of diastolic pressure ratio (dPR) and Pd/Pa for physiological assessment of ischemic stenotic lesions.

Measurement of FFR requires simultaneously monitoring the blood pressures proximal and distal to a lesion while inducing hyperemia. dPR is a measure of the diastolic portion of the hemodynamic waveform and can be used by the physician to perform a physiologic assessment without inducing hyperemia in the patient.

INDICATIONS FOR USE

The ACIST RXi® System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus® Catheter is intended for use with the ACIST RXi System.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed RXi System with dPR software update is substantially equivalent to the predicate RXi System (K190473). The fundamental technology and principle of operation of the RXi System are unchanged from the predicate device. The only change to the RXi System is a software update and updated labeling to describe the additional software features. The software update to the RXi console will allow the user to select between the existing hyperemic-induced FFR measurement and a new modality of non-hyperemic dPR measurement.

The following technological difference exists between the subject and predicate device:

- Software update to allow the current system to compute and display a non-hyperemic diastolic pressure ratio (dPR) index for physiological assessment.

The subject device (RXi® System with dPR modality) has the same intended use, design, materials, and energy source as the legally marketed predicate device (RXi® System) cleared by FDA under premarket notification K190473. While the subject device introduces an additional technological characteristic (the dPR modality), verification and validation testing demonstrate that this technological difference does not raise new issues of safety and effectiveness.

The identified questions of safety and efficacy apply to both the new device and the predicate. Performance testing confirmed the software update for dPR does not raise any different questions of safety and efficacy and therefore the RXi System with dPR meets substantial equivalence requirements with regards to the legally marketed predicate RXi System (K190473).

PERFORMANCE DATA

The risk management process has been used to evaluate the dPR software update to the RXi System in accordance with the guidelines set forth in ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices. The risk analysis for the RXi System with dPR has taken into consideration the medical device vigilance data and product experience of the predicate RXi System. All residual risks that relate to the software update to include dPR have been taken into consideration. All RXi System and software residual risks are outweighed by potential benefits and are therefore acceptable.

Verification and Validation testing was completed to establish the RXi system console software with dPR functionality meets specifications and performs as intended.

Software verification included unit testing, software integration, and GUI-level verification.
ACIST validated the diagnostic performance of the RXi software update to introduce the dPR modality by demonstrating the agreement between the non-hyperemic RXi dPR index and the non-hyperemic instantaneous wave-free ratio (iFR) modality of the FDA-cleared reference device, Volcano s5/s5i CORE Mobile (K173860) as compared to FFR using a dataset collected in a prospective clinical study.

The diagnostic performance evaluation used a non-clinical bench top hemodynamic test fixture to reproduce resting and hyperemic clinical waveform recordings from the prospective CONTRAST[1] clinical study. Resting and hyperemic pressure readings from each recorded waveform were measured using the ACIST RXi System and Navvus Catheter, and in parallel, the Philips Verrata PLUS wire and Philips (Volcano) CORE Mobile system. A statistical analysis of the collected datasets demonstrated all three pre-determined primary endpoints (diagnostic accuracy, sensitivity, and specificity) were met.

Compared to FFR measurements (cutpoint 0.80), the accuracy of dPR (cutpoint 0.89) was 76.39%, and the accuracy of iFR (cutpoint 0.89) was 78.46%, resulting in a diagnostic accuracy difference of -2.08%. The sensitivity for dPR vs iFR was 99.68% and was higher than the pre-determined performance goal of 90%. The specificity for dPR vs iFR was 88.92% and was higher than the pre-determined performance goal of 84%. The diagnostic accuracy of dPR compared to iFR was 93.89%, confirming the agreement of diagnostic accuracy between dPR and iFR compared to FFR and supporting a conclusion of substantial equivalence.

CONCLUSIONS

The results from the tests mentioned above demonstrate that the technological and performance characteristics of the proposed RXi System are comparable to the predicate device. The results of testing and outputs of the risk management process support the safety and effectiveness of the dPR software upgrade and ensure the subject device can perform in a manner equivalent to the predicate device with the same intended use. The results of the verification/validation tests and the risk analysis have demonstrated that the software upgrade to allow calculation of dPR does not add any new questions of safety and efficacy and is therefore substantially equivalent to the predicate RXi System (K190473) and reference device, Volcano iFR Modality (K173860).

SUBSTANTIAL EQUIVALENCE

The new proposed device is the RXi System including a new dPR modality. The predicate device is the currently marketed RXi System without a dPR modality (K190473). The Navvus Catheter and accessories included in K190743 are not affected by this submission. The only change to the RXi System is to add a non-hyperemic diastolic pressure ratio (dPR) calculation for added functionality in the software capabilities and updated labeling to describe the additional software features. The reference device is the marketed Volcano s5 system (K173860), specifically the iFR modality. The purpose of the reference device iFR modality is to demonstrate safety and effectiveness of the dPR modality.

Equivalence of Intended Use:

[1] Johnson NP, Jeremias A, Zimmermann FM, et al. Continuum of vasodilator stress from rest to contrast medium to adenosine hyperemia for fractional flow reserve assessment. *JACC: Cardiovascular Interventions.* 2016;9(8):757-767

Indications for the device remain unchanged from the predicate device. The reference device contains similar indications for the pressure measurement modality.

Equivalence of Technological Characteristics:

The only difference between the subject and predicate devices is the addition of the dPR modality embedded into the software of the RXi System. Otherwise, the subject and predicate device share identical technological characteristics. Performance testing has confirmed the equivalent diagnostic performance of the subject device dPR modality relative to the iFR modality of the reference device.

No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

Safety and Effectiveness:

The identified questions of safety and efficacy apply to both the new device and the predicate; therefore, the new device does not raise different questions of safety and efficacy. Specifically, a resting index calculation poses less risk to the patient as there is no need to use a hyperemic agent. The proposed device does not raise any different questions of safety and efficacy.

Conclusion:

The proposed device, RXi System with dPR software upgrade, was shown to be substantially equivalent to the legally marketed predicate RXi System (K190473), except for a software change introducing the dPR modality.

The safety and effectiveness of the RXi System dPR modality has been shown to be substantially equivalent to the iFR modality of marketed device K173860.

Feature		**Proposed Device – RXi System**	**Predicate Device – RXi System**	**Reference Device – Volcano iFR**
Regulatory Information	*Name*	RXi System	RXi System	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System
	510(k)#	Not yet assigned	K190473	K173860
	Predicates	K190473	K132474	K133323 K170133
	Classification Name	Catheter, pressure monitoring, cardiac	Catheter, pressure monitoring, cardiac	Ultrasonic Pulsed Echo Imaging System
	Product Code & Regulation Number	DXO, OBI 21 CFR 870.2870, 21 CFR 870.1200	OBI, DXO 21 CFR 870.1200, 21 CFR 870-2870	IYO 21 CFR 892.1560
	FDA Classification	II	II	II
	Classification Panel	Cardiovascular	Cardiovascular	Radiology

Feature		Proposed Device – RXi System	Predicate Device – RXi System	Reference Device – Volcano iFR
Indications for Use	*Indications for Use/ Intended Use*	The ACIST RXi System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus Catheter is intended for use with the ACIST RXi System.	The ACIST RXi System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus Catheter is intended for use with the ACIST RXi System.	The FFR v2.5 Modality of the s5/s5i/Core and Core Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR Modality is intended to be used in conjunction with currently marketed Volcano Pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used as for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenosis such as, multiple lesions or diffuse disease.
	Contraindications	The ACIST Navvus Catheter is contraindicated for use in the cerebral vasculature.	The ACIST Navvus Catheter is contraindicated for use in the cerebral vasculature.	Use of the Volcano system is contraindicated wherever tissue or organ damage is a reasonable probability. The catheter is not for fetal use.

Feature		Proposed Device – RXi System	Predicate Device – RXi System	Reference Device – Volcano iFR
	Fundamental Scientific Technology	A device with an integrated pressure sensor used in the real-time calculation of FFR or dPR based on patient blood pressure	A device with an integrated pressure sensor used in the real-time calculation of FFR based on patient blood pressure	A device with an integrated pressure sensor used in the real-time calculation of FFR or dPR based on patient blood pressure
Technological Characteristics	Prescription Use	Rx Only	Rx Only	Rx Only
	System Components and accessories	Console with embedded software, Navvus Catheter connection port, FISO signal conditioner, touchscreen, and graphical user interface (GUI), and accessories (mount, cart, hemodynamic cables, power supply and cord, AO interface box)	Console with embedded software, Navvus Catheter connection port, FISO signal conditioner, touchscreen, and graphical user interface (GUI), and accessories (mount, cart, hemodynamic cables, power supply and cord, AO interface box)	This reference device is a larger system with additional capabilities not related to this submission.
	Pressure Sensing and Signal Transmission Technology	EEPROM in the Navvus Catheter connector communicates with the FISO board in the RXi Console	EEPROM in the Navvus Catheter connector communicates with the FISO board in the RXi Console	Pressure measurement is captured through the use of pressure wires.
	Connected Device(s)	Navvus/Navvus II Catheter	Navvus/Navvus II Catheter	SmartWire II, PrimeWire Prestige, PrimeWire Prestige Plus, Verrata, Verrata Plus
	Auto-Zeroing	Yes	Yes	Yes
	Diastolic Resting Indices	dPR, Pd/Pa	Pd/Pa	iFR
	User Interface Displays	• Audible and visual alarm • LED Status Indicators • Console touchscreen	• Audible and visual alarm • LED Status Indicators • Console touchscreen	• Bedside: Touchpad or joystick • Control room: Console
	Intended Operating Environment	• Angiographic Catheterization Lab • Interventional Radiology Lab • Operating Room (OR)	• Angiographic Catheterization Lab • Interventional Radiology Lab • Operating Room (OR)	• Angiographic Catheterization Lab • Interventional Radiology Lab • Operating Room (OR)
	Electrical Isolation (UL Classification)	Class II (double isolation)	Class II (double isolation)	Class I (functional ground)
	Operating Pressure Range	-30 to +300 mmHg	-30 to +300 mmHg	-30 to 300 mmHg

Feature		Proposed Device – RXi System	Predicate Device – RXi System	Reference Device – Volcano iFR
	Zero Drift	≤ 7 mmHg over one hour	≤ 7 mmHg over one hour	5 mmHg / 10 minutes
	Pressure Accuracy	3 mmHg or 3% of reading	3 mmHg or 3% of reading	Not Specified
	Calculation types/ Physiological Measurements	FFR, Pd/Pa and dPR	FFR and Pd/Pa	FFR, iFR
	Hyperemic agent	Not required for dPR Required for FFR	Required for FFR	Not required for iFR Required for FFR
	Resting Indices Wave Selection	Automatically selected	N/A	Automatically selected
	Resting Indices Cutoff Point	0.89	N/A	0.89
	Aortic Input	100 mmHg/V	100 mmHg/V	High Level (100 mm Hg/V)
	Distal Pressure Output	5µV/V/mmHg	5µV/V/mmHg	Low Level 5 uV/mmHg
	Software Application	Microsoft Windows CE Real-Time Operating System RTOS	Microsoft Windows CE Real-Time Operating System RTOS	Not specified
	Signal Acquisition	8 milliseconds	8 milliseconds	Not specified
	Real-Time Clock and Battery	Console software contains a real-time clock and battery back-up	Console software contains a real-time clock and battery back-up	Not specified
	Communication Protocols	Serial Peripheral Interface (SPI) is used for intra-board communications within the RXi Console, TTL serial port between FISO signal conditioner and RXi console	Serial Peripheral Interface (SPI) is used for intra-board communications within the RXi Console, TTL serial port between FISO signal conditioner and RXi console	Not specified