September 13, 2019

ACIST Medical Systems, Inc.
Sherri Mellingen
Principal Regulatory Affairs Specialist
7905 Fuller Road
Eden Prairie, Minnesota 55344

Re: K190473
Trade/Device Name: ACIST Rapid Exchange (RXi) System and Navvus II MicroCatheter
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, OBI
Dated: August 13, 2019
Received: August 14, 2019

Dear Sherri Mellingen:

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,

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)*
K190473

Device Name
ACIST Rapid Exchange (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.

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

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510(k) Summary

Date Prepared: 2/26/2019

Submitters Name / Contact Person

510k Submitter Address
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General Information	
Trade Name:	ACIST Rapid Exchange (RXi) System and Navvus II MicroCatheter
Common / Usual Name:	Cardiovascular Pressure Measurement System and Navvus Catheter
Classification:	Class 2 per 21 CFR 870.2870
Product Code:	OBI, DXO
Predicate Device:	ACIST RXi® System and Navvus Catheter

Device Description

1. Navvus II

The ACIST Navvus II MicroCatheter is a single-lumen monorail catheter designed to be used with standard 0.014 in (0.36 mm) guidewires in the arterial vasculature. The MicroCatheter is compatible with the ACIST RXi family of system hardware which includes the RXi System and RXi Mini. Features unique to each system are denoted specifically.

The Navvus II MicroCatheter distal shaft is 26 cm in length with a pressure sensor located 5 mm from the distal tip. The elliptical distal shaft is 1.68 x 1.91F (0.020 in x 0.025 in) up to 10 mm from the distal tip; a maximum profile of 2.7F (0.036 in) occurs at the pressure sensor. The distal shaft smoothly tapers over the pressure sensor and down to the tip accepting the guidewire. A radiopaque marker band is located 2.5 mm from the distal tip.

The shaft proximal to the monorail section is 2.4F, allowing use in 5F or larger guide catheters. Two white positioning markers are located at 80 cm and 100 cm from the distal tip. The pressure sensor on the catheter utilizes optical sensing technology. Both the optical pressure signal and information for auto calibration are transmitted from the catheter to the RXi hardware.

2. RXi System

The ACIST RXi System is designed to provide hemodynamic information for the diagnosis and treatment of coronary and peripheral artery disease. The system is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display fractional flow reserve (FFR) and resting Pd/Pa.

FFR and resting Pd/Pa supplement the visual data provided by angiography and provides an assessment of the lesion severity.

Measurement of FFR and resting Pd/Pa requires simultaneously monitoring the blood pressures proximal and distal to a lesion. The ACIST RXi System includes a single-use MicroCatheter with a pressure sensor for acquisition of the distal pressure. The proximal pressure is acquired via the guide catheter which is monitored by the ACIST RXi System via an interface to the hospital's hemodynamic monitor.

Pd/Pa is the ratio of distal coronary arterial pressure to aortic pressure, measured at resting conditions. The physician may then use the resting Pd/Pa value, along with knowledge of patient history, medical expertise and clinical judgment to determine if an additional measurement of FFR during hyperemia or therapeutic intervention is indicated.

Intended Use / Indications

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.

Comparison of Technological Characteristics

The RXi System is identical to the predicate as there have been no design changes since the device was originally cleared. The Pd/Pa function has always existed on the device as this change is simply to include it in the labeling. The Navvus II differs from the predicate device with regard to the tip OD (0.06mm difference) and the distance from the distal end of the sensor to the marker band (0.10 difference). Design verification testing demonstrated that these two small differences did not affect the performance of the device and that the subject device and the predicate device were substantially equivalent. The Navvus II Catheter is substantially equivalent to the legally marketed predicate device in design, intended use, intended population, principles of use, materials, size and sterility.

Table 1: Comparison with Predicate			
	Subject Device	**Predicate Device**	**Comparison of K132474 to Subject Device**
510(k) #	TBD	K132474	
Intended Use / Indications	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 MicroCatheter is intended for use with the entire family of ACIST RXi Systems.		Same
Principles of Use	Calculates FFR and Pd/Pa based on simultaneous acquisition of pressure from two transducers: • The flexible distal tip of the catheter that contains the optical pressure sensor is advanced over the proximal end of the 0.014 in (0.36 mm) guidewire that is already in place in the distal vasculature. • The Navvus catheter is advanced over the wire and positioned with the radiopaque marker in the coronary ostium, 3 mm outside the tip of the guide catheter. • Equalization must take place with the Navvus Catheter distal tip just outside the tip of the guide catheter. Pressure is measured less than 3 mm proximal from the marker band visible under fluoroscopy. • The guide catheter is flushed with saline solution. Then the Navvus Catheter sensor is advanced past the lesion under study.		Same
Display Features	Navvus distal (Pd) and proximal/aortic (Pa) pressure, Pd/Pa, and FFR		Same
Intended Anatomical Location	Coronary and peripheral vasculature		Same
Configuration	Navvus Catheter is a 0.022” catheter with and integrated pressure sensor that is used in the real-time calculation of FFR and Pd/Pa together with a detachable cable for connection to a diagnostic computer.		Same
Coating	No		Same
Marker Band?	Yes – 2.5mm from distal tip		Same
Maximum Tip OD	Tip OD 0.75mm MAX	Tip OD 0.69mm MAX	Differs 0.06mm

Table 1: Comparison with Predicate			
	Subject Device	**Predicate Device**	**Comparison of K132474 to Subject Device**
Distal End of Sensor to Markerband	2.31+/- 0.25mm	2.41+/- 0.25mm	Differs by 0.10mm
Effective (Working) Length	145 cm to 155 cm		Same
Compatible Guidewire Diameter (max)	0.014"		Same
Single use, sterile?	Yes		Same
Sterilization method	Ethylene Oxide		Same
Intended Population	This product is designed for use in adult patients identified by a physician as suitable candidates for vascular pressure measurement after taking into consideration the patient's anatomy and health status.		Same

Non-Clinical Bench Testing

The following non-clinical bench testing was completed on the Navvus II MicroCatheter:

Dimensional and Visual Inspections
Static Accuracy
Tortuous Path
Durability
Tensile Strength

Pd/Pa Clinical Post-Market Analysis and Supported Literature

The expected FFR value in a normal vessel without a stenotic lesion or obstruction to blood flow is a value of 1.0. Based on clinical evidence, a threshold or cutpoint value of ≤ 0.80 is commonly considered for treatment with a therapeutic intervention, while a value > 0.80 is commonly considered for deferment. An established, clinically evident Pd/Pa threshold or cutpoint such as this is indeterminate, but guidance for use of Pd/Pa for clinical decision making may be considered by referring to the existing, supportive clinical evidence from multiple diagnostic accuracy studies performed on resting Pd/Pa.

A recent meta-analysis was reported by Maini et al., based on published resting Pd/Pa diagnostic accuracy studies[2] which examined the overall diagnostic accuracy of Pd/Pa compared to FFR. The meta-analysis reported on 14 studies with an optimal cutpoint ranging from 0.875 to 0.96 and resulted in cutpoints from 0.91 to 0.93 in 12 of the 14 studies in the meta-analysis.

The ACIST-FFR Pd/Pa Post-hoc Sub-Group Analysis[1] identified an optimal cutpoint of 0.91. The cutpoint was derived from a post-hoc receiver operating characteristic (ROC) curve analysis using an FFR cutoff value of ≤0.80 measured with the Navvus MicroCatheter to define stenosis. The 0.91 cutpoint is within the range of 0.91 to 0.93 as was reported in 12 of the 14 studies in the Maini et al., meta-analysis.

Standards

The following is a summary of the standards used in testing for the RXi System and Navvus II MicroCatheter:

Table 3: Standards used in non-clinical bench testing

Test	Industry Standards	FDA Recognition Number, Version and Date
Design Verification	EN ISO 13485:2016, Medical Devices, Quality Management Systems	Not recognized by FDA
Device Performance	EN ISO 13485:2016, Medical Devices, Quality Management Systems	Not recognized by FDA
	ISO 10555-1, Sterile and Single Use Intravascular Catheters General Requirements	6-301 8/14/2015
Risk Management	EN ISO 14971, Application of Risk Management to Medical Devices	5-40 6/27/2016
Medical Electrical Equipment	IEC 60601-1-2:2014, Medical Electrical Equipment	19-8 9/17/2018
Animal Model	FDA 21 CFR: Part 58 Good Laboratory Practice Regulations	N/A
Packaging & Shelf Life	ISO 11607-1:2006/2010, 11607-2:2006 Packaging for Sterilized Medical Devices	14-454, 14-455 1/27/2015
Biocompatibility	ISO 10993-1: 2009 Biological Evaluation of Medical Devices	2-220 7/26/2016
Sterilization	ISO 11135:2014 Medical Devices – Validation of Routine Control of Ethylene Oxide Sterilization	14-452 4/4/2016

Product Codes

The following product codes are similar to the predicate and subject device (product code OBI) as the devices are classified in accordance with regulation 870.1200: DQO, NLI, NUI, OBJ, OES, OEZ, OFN, OGZ, ORD. The secondary product code, DXO, is regulated in accordance with regulation 870.2870 and has no similar product codes.

Substantial Equivalence

Results of design verification testing on the Navvus II MicroCatheter demonstrate that the device is substantially equivalent to the predicate device. The subject device has been evaluated through bench testing. All test results met documented acceptance criteria and demonstrated the Navvus II MicroCatheter is substantially equivalent to the predicate device. Finally, the ACIST-FFR Pd/Pa Sub-Group Post-Hoc Analysis, in which all pressure tracings were acquired by the ACIST Navvus MicroCatheter, gave additional information on the clinical use of Pd/Pa and provided further information as compared to the cutpoint range presented in the Maini meta-analysis.

[1] Thackery, Lisa., Rorke, Becky., Larson, Janet A., Pd/Pa, Sub-Group, Post-hoc analysis of data from the ACIST-FFR clinical study which assessed catheter-based interrogation and standard techniques for Fractional Flow Reserve Measurement. Original data set analysis published in: Circ Cardiovasc Interv. 2017 Dec; 10 (12). e005905

[2] Maini R, Moscona J, Sidhu G, et al. Pooled diagnostic accuracy of resting distal to aortic coronary pressure referenced to fractional flow reserve: The importance of resting coronary physiology. Journal of Interventional Cardiology. 2018;31(5):588-598. doi:10.1111/joic.12517.

[3] Ligthart Jurgen, Masdjedi Kaneshka, Witberg Karen, et al. Validation of Resting Diastolic Pressure Ratio Calculated by a Novel Algorithm and Its Correlation With Distal Coronary Artery Pressure to Aortic Pressure, Instantaneous Wave–Free Ratio, and Fractional Flow Reserve. Circulation: Cardiovascular Interventions. 2018;11(12):e006911. doi:10.1161/CIRCINTERVENTIONS.118.006911.