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Section 6 — 510(k) Summary [21 CFR 807.92]

Date the Summary was Prepared

January 28, 2014

510(k) Submitter's Name and Address

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Sterilization Facility Sterigenics US, Inc. 7775 S Quincy St. Willowbrook, IL 60527 Establishment Registration Number: 1450293
Console Manufacturing Facility ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 Establishment Registration Number: 2134243
Catheter Manufacturing Facility MedVenture 2301 Centennial Blvd. Jeffersonville, IN 47130 Establishment Registration Number: 1222140
Device Classification Names Transducer, Pressure, Catheter Tip and Catheter, Pressure Monitoring, Cardiac
Device Common/Usual Name Catheter Tip Pressure Transducer and Diagnostic Intravascular Catheter
Device Trade/Proprietary Name Rapid Exchange (RXi) System and Navvus Catheter
Product Codes DXO and OBI
Classification of Device Class II 21 CFR 870.2870 and 870.1200

Predicate Device(s)

Device Name	Submission Number	Clearance Date
Radi Analyzer® and PressureWire® Sensor (RADI Medical Systems, St. Jude Medical, Minnesota, USA)	K062769	December 4, 2006

Device Description

The Rapid Exchange (RXi) System and Navvus Catheter are intended to provide hemodynamic measurement information for use in the diagnosis and treatment of coronary or peripheral artery disease. When used in catheterization and related cardiovascular specialty laboratories, the Rapid Exchange (RXi) System and Navvus Catheter will compute and display physiological parameters based on the output of an optically-based pressure measuring sensor.

The Rapid Exchange (RXi) System and Navvus Catheter consist of a single patient use, catheter-based sensing device, a hardware system containing embedded software, a user interface touchscreen, and electronics for converting measured pressure signals into Fractional Flow Reserve (FFR) measurements. The intravascular blood pressure sensor is optically-based and adhered to the end of a fiber optic. The sensor and fiber optic are integrated into a monorail catheter, which connects to the system to deliver the measured pressure data.

Proposed Intended Use & Indication for Use

The Intended Use/Indication for Use of the Rapid Exchange (RXi) System and Navvus Catheter is as follows:

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

Summary of the Technological Characteristics to the Predicate Device(s)

The Rapid Exchange (RXi) System and Navvus Catheter employs many of the same technology characteristics as the predicate device to perform coronary pressure and fractional flow reserve (FFR) measurements. The Rapid Exchange (RXi) System and Navvus Catheter includes an intracoronary pressure measurement system that would allow the physician to use the best guidewire for the patient's anatomy and would facilitate access to coronary lesions. Using the Rapid Exchange (RXi) System and Navvus Catheter could avoid multiple guidewire exchanges if the patient went on to PCI after the FFR measurement, because the physician could use the same guidewire for the PCI.

The Rapid Exchange (RXi) System and Navvus Catheter and the predicate are intended for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The Rapid Exchange (RXi) System, Navvus Catheter and predicate are designed to fit inside a percutaneous guiding catheter for the purpose of directing the catheter through a vessel. The signal output from the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on pressure e.g. Fractional Flow Reserve (FFR).

The predicate devices are 0.014" guidewires with an integrated pressure sensor, together with a detachable cable for connection to a diagnostic computer.

The devices are for single use and are not to be re-sterilized.

The Rapid Exchange (RXi) System and Navvus Catheter device modifications are deemed substantially equivalent to the RADI PressureWire Sensor, as there are no differences in the product performance, device indications for use/intended use and/or device functional scientific technology. The subject device uses the same surgical approach procedures as the predicate device.

ACIST Medical Systems considers the Rapid Exchange (RXi) System and Navvus Catheter product performance to be significantly equivalent to the predicate device, Radi Analyzer and PressureWire Sensor.

Characteristic	Radi Analyzer® and PressureWire® (RADI Medical Systems, St. Jude Medical, Minnesota, USA) (K062769)	ACIST Rapid Exchange (RXi) System and Navvus Catheter
Intended Use	PressureWire is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on pressure or temperature, e.g. Fractional Flow Reserve (FFR).	The ACIST Rapid Exchange (RXi) System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The Navvus Catheter is intended for use with the ACIST RXi System.
Conditions of Use	• Operating temperature 15°C to 30°C (59°F to 86°F) • Transport temperature -40°C to 70°C (-40°F to 158°F) • Storage temperature: Room temperature • Relative humidity operating 30-75%	•Operating temperature 18°C to 30°C • Transport temperature -29°C to 60°C • Storage temperature: Room temperature • Relative humidity operating 10-95% non-condensing
Specifications and Properties	• Pressure Accuracy: +/-1mmHg plus +/-1% of reading (over the pressure range -30 to 50mmHg); +/-3% of reading (over the range 50 to 300mmHg) • Pressure range: -30 to 300mmHg • Frequency response: 0-25 Hz • Zero thermal effect: 0.3 mmHg/degC • Sensitivity thermal effect: 0.3%/degC • Zero drift: <7 mmHg/h	•Pressure Accuracy: +/- 3% of reading or +/- 3 mmHg, whichever is greater • Pressure range: -30 to 300mmHg • Frequency response: Not specified • Zero thermal effect: <0.4 mmHg/degC • Sensitivity thermal effect: Not specified Zero drift: <7 mmHg/h
Design	Strain gauge type pressure sensor embedded in a guidewire.	Fiber optic type pressure sensor embedded in a 0.014" compatible rapid exchange catheter.
Methods	Device is introduced as a guidewire and placed in the vessel of interest.	Device is introduced over a guidewire placed in the vessel of interest.
Principles of Operation	Calculates FFR based on simultaneous acquisition of pressure from two transducers: • Distal pressure from the sensor. • Aortic pressure from a transducer reading pressure in the ostium.	Calculates FFR 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 Navvus catheter sensor is advanced past the lesion under study. To measure FFRmin or make other measurements using the RXi system, refer to the RXi System User's Guide for further instruction regarding the use of the RXi System for recording FFR values using the Navvus Catheter.

Summary of Non-Clinical Testing

The non-clinical testing included the assessment of the physical properties of the Rapid Exchange (RXi) System and Navvus Catheter and its ability to achieve its intended use and is substantially equivalent to the predicate device, Radi Analyzer and PressureWire Sensor. Bench testing of the device confirmed the suitability of the device for its intended use.

Animal testing provided evidence to confirm the same technology characteristics as the predicate device to perform coronary pressure and fractional flow reserve (FFR) measurements.

Biocompatibility assessment was to ensure that the biocompatibility has been established for the Rapid Exchange (RXi) System and Navvus Catheter; based on the similarity of the materials as the commercialized predicate device.

The following table is a summary, not limited to, the non-clinical testing conducted in accordance to industry standards/regulations:

Test	Industry Standards
Design Verification	Quality System Requirements FDA 21 CFR Part 820.20 EN ISO 13485: 2003; Design Controls FDA 21 CFR Part 820.30
Device Performance	Quality System Requirements FDA 21 CFR Part 820.20 EN ISO 13485: 2003; Design Controls FDA 21 CFR Part 820.30
Animal Model	FDA 21 CFR: Part 58 Good Laboratory Practice Regulations
Packaging	ISO 11607: 2006 Part 1 and Part 2: Packaging for Terminal Sterilized Medical Devices
Shelf Life	ISO 11607: 2006 Part 1, 6.4 Stability Testing
Biocompatibility	ISO 10993-1: 2009 Biological Evaluation of Medical Devices.
Sterilization	ISO 11135: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization and EN ISO 13485.

The proposed Rapid Exchange (RXi) System and Navvus Catheter device performance and fundamental scientific technology remains unchanged to the predicate device. The proposed modifications do not change to the coronary pressure and fractional flow reserve (FFR) measurements in the legally marketed predicate device.

Summary of Clinical Testing

A prospective, observational, multi-center study was conducted. The primary objectives of the study were to assess the relationship in FFR measurements between the Navvus catheter and the Radi Pressure wire (Radi), including rate of device success defined as a valid FFR measurement by the Navvus Catheter where a valid FFR measurement was taken using the Radi. The study used paired measurements from the Navvus catheterand Radi within subjects as controls. Pressure measurements were assessed intra-operatively; subjects were evaluated for safety events through hospital discharge.

Three centers participated and enrolled 58 subjects. Patients with single or multi-vessel coronary artery disease indicated for FFR and a vessel reference diameter of ≥ 2.5 mm were eligible.

The average subject was a sixty-five (65) year old male (80%), ranging in age from 42-86 years. The majority of subjects had a history of dyslipidemia (86%), hypertension (74%) and angina (64%).

Study procedures were performed through the femoral (32%) or radial (68%) artery. Reference vessel diameters ranged between 2.5 and 5.5 mm (average 3.2 ± 0.6 mm) with percent diameter stenosis ranging from 40 - 90% (average 57.2 ± 10.0%).

Results of Clinical Investigation:	In summary, the results of this study are as follows: • The RXI system was 100% successful in taking valid FFR measurements in all lesions in which the Radi was able to take valid FFR measurements. • The overall bias, as determined from a Bland-Altman analysis, was -0.01. • Using a Bland-Altman analysis, the observed 95% limits of agreement was -0.13 to 0.10. • The Kolmogorov-Smirnov test for linearity showed a cumulative p-value of 0.72, meeting success criteria of being > 0.1. • The intercept determined by a Passing-Bablok linear regression between FFR measurements made using RXi system and that made using Radi had a 95% confidence interval of -0.15 to 0.19, meeting success criteria of the interval containing 0. • The slope determined by a Passing-Bablok linear regression between FFR measurements made using RXi system and that made using Radi showed a 95% confidence interval of 0.76 to 1.17, meeting success criteria of the interval containing 1. • Receiver Operator Curves, using the first measured Radi FFR measurement as the standard, created for both the Navvus catheter measured FFR and the last Radi FFR demonstrated very similar areas under the curve (87.4% and 88.1%, respectively). • The RXi System demonstrated a statistically significant lower rate of drift compared to the Radi system, both for mean drift (0.02 ± 0.02 for RXi vs. 0.06 ± 0.12 for Radi) and clinically relevant drift (13% vs. 33% rate of occurrence). • This clinical study also demonstrated a very good safety profile. Although serious adverse events occurred during five subject's hospitalization none of these events were related to the RXi system. In a similar fashion, none of the 17 reported adverse events were device related. Eleven of the 17 were related to the procedure, including: hematomas, mild hemorrhage, elevated cardiac enzymes, nausea, vasovagal reaction, headache, hypokalemia, temporary rhythm disturbances and wheeze. All of the adverse events were mild to moderate in nature.

Substantial Equivalence

The proposed Rapid Exchange (RXi) System and Navvus Catheter device uses the same surgical approach procedures as the predicate device.

The proposed Rapid Exchange (RXi) System and Navvus Catheter device and the predicate device have similar indications for use/intended use, similar implant materials, similar sterilization methods; and similar delivery characteristics.

The device performance and fundamental scientific technology remains unchanged. The differences between the proposed device and the predicate device do not have any negative effect on the safety and effectiveness of the device.

The non-clinical test and clinical results conclude that the Rapid Exchange (RXi) System and Navvus Catheter to be substantially equivalent to the predicate device, Radi Analyzer and PressureWire Sensor.

Conclusion

Based on ACIST Medical Systems assessment of the Rapid Exchange (RXi) System, Navvus Catheter and predicate device, we conclude that the Rapid Exchange (RXi) System and Navvus Catheter contains technological features that do not differ significantly from the currently marketed device. Bench testing completed according to the Verification and Validation Test Plans confirms that the design specifications for the Rapid Exchange (RXi) System and Navvus Catheter have been met and that the device meets the applicable requirements for the safety and performance standards cited. Therefore, ACIST Medical Systems concludes that the Rapid Exchange (RXi) System and Navvus Catheter are substantially equivalent to the legally marketed predicate device subject to this 510(k) based on design, performance, characteristics, and indication for use and does not introduce any new questions regarding safety or effectiveness of the product for its proposed intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 30, 2014

Acist Medical Systems
Matthew Stepanek
Principal Regulatory Affairs Specialist
7905 Fuller Road
Eden Prairie, MN 55344 US

Re: K132474
Trade/Device Name: Rapid Exchange (RXi) System and Navvus Catheter
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer, Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DXO, OBI
Dated: December 19, 2013
Received: December 20, 2013

Dear Mr. Stepanek:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 Statement of Indications for Use

510(k) Number: K132474

Device Name: Rapid Exchange (RXi) System and Navvus Catheter

Indications for Use: The ACIST Rapid Exchange (RXi) System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The Navvus Catheter is intended for use with the ACIST RXi System.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S.
Date: 2014.01.30 15:14:14 -05'00'