August 14, 2019

Zurich Medical Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K190852
Trade/Device Name: Zurich Pressure Guidewire System Model 100
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, DQK, DSK, DQA
Dated: June 19, 2019
Received: June 24, 2019

Dear Mark Job:

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)*
K190852

Device Name
Zurich Pressure Guidewire System

Indications for Use *(Describe)*
Zurich Pressure Guidewire System is indicated to measure physiological parameters in the coronary and peripheral blood vessels and in the heart. Zurich Pressure Guidewire System is also indicated to direct a catheter through a blood vessel.

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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6.0 510(K) SUMMARY

6.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: February 16, 2019

6.1.1 CONTACT INFORMATION

Sponsor/Manufacturer

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6.1.2 DEVICE INFORMATION

Trade Name	Zurich Pressure Guidewire System Model 100™
Common Name	Zurich Pressure Guidewire System
Classification Name	Catheter Tip Pressure Transducer
Regulation Number(s):	870.2870, 870.1330 (interventional guidewire) 870.1425, 870.1110 (portable display)
Class	II
Classification Panel	Cardiovascular
Product Code	DXO, DQX (interventional guidewire) DQK, DSK (portable display)

6.2 PREDICATE DEVICES

The Zurich Pressure Guidewire System Model 100™ is substantially equivalent to the following:

- K131452 (Abbott Laboratories) St. Jude Medical Systems AB, PressureWire™ Certus™ (interventional guidewire)
- K092105 (Abbott Laboratories) Radi Medical Systems AB, RadiAnalyzer™ Xpress (portable display)

6.3 DEVICE DESCRIPTION

The Zurich Pressure Guidewire System Model 100™ ("Zurich Pressure Guidewire System") consists of a 0.014" (0.36 mm) diameter, 180 cm long Interventional Guidewire with a high fidelity sensor located immediately beyond the 3 cm shapeable radiopaque tip and a uniquely paired Portable Display. The signals from the sensor can be used to measure blood pressures and calculate Fractional Flow Reserve (FFR). The Guidewire is connected to the Portable Display via the Handle. The distal end has hydrophilic coating. The Portable Display also has an AO Cable that may be used to connect to the Zurich Medical Accessory Cable for AO pressure signal.

6.4 INTENDED USE

Zurich Pressure Guidewire System is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output of the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on pressure, e.g. Fractional Flow Reserve (FFR).

6.5 INDICATIONS FOR USE

Zurich Pressure Guidewire System is indicated to measure physiological parameters in the coronary and peripheral blood vessels and in the heart. Zurich Pressure Guidewire System is also indicated to direct a catheter through a blood vessel.

6.6 TECHNOLOGICAL CHARACTERISTICS

The Zurich Pressure Guidewire System Model 100 is designed for use as an adjunct to conventional angiographic procedures, which identify intermediate lesion(s) to be examined further. FFR is a calculation that has been clinically proven to assist in determining whether to treat or not to treat these intermediate lesions.

The Zurich Pressure Guidewire System Model 100 consists of the following:

- 0.014" standard guidewire
- Pressure sensor located 3 cm proximal to the distal tip
- Disposable battery powered portable display

6.7 PERFORMANCE DATA (SUMMARY OF NON-CLINICAL TESTING)

The Zurich Pressure Guidewire System has been tested and meets all its physical and performance specifications. These include:

- Electromagnetic Compatibility testing per IEC 60601-1-2 Edition 4.0 2014-02
- Electrical Safety testing per AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012
- Biocompatibility testing per ISO 10993-1:2009 for external communicating device with short-term contact duration (<24 hours) with circulating blood
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Systemic Toxicity
    - Hemolysis -Direct and Indirect Contact
    - Complement Activation
    - Thromboresistance
    - Materials Mediated Pyrogenicity
    - Genotoxicity
- Packaging Validation per ISO 11607-1:2006 after distribution simulation per ASTM D4169-16
- Labeling per FDA General Device Labeling Requirements 21 CFR Part 801 and Unique Device Identification Labeling Requirements 21 CFR Part 830
- Sterilization per ISO 11135:2014 and ISO 10993-7:2008
- Human Factors per IEC 62366-1:2015
- Shelf Life Testing per ASTM F1980-16
- Animal studies were carried out under full GLP guidelines. All requirements were met as set forth in the study protocols for Zurich Pressure Guidewire System.
- Software Testing and Bench Verification Testing for Interventional Guidewire, Portable Display, and System included:
    - Diameter
    - Vascular Device Compatibility
    - Tensile
    - Kink
    - Pushability
    - Torque
    - Flexibility
    - Coating Uniformity and Durability
    - Corrosion
    - Lubricity
    - Fatigue
    - Fracture
    - Dimensional

- Particulate
- Software verification and validation testing was conducted as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

The testing showed that the device meets specifications before and after aging, indicating that the device is as safe and effective as the predicate devices. See Section 19 for performance specification details.

6.8 SUBSTANTIAL EQUIVALENCE

Zurich Pressure Guidewire System is substantially equivalent to the presently marketed predicate device, K131452, St. Jude Medical PressureWire Certus Guidewire (interventional guidewire) and K092105 RadiAnalyzer Xpress (portable display) in terms of intended use, indications for use, operational characteristics, and technology characteristics. The Zurich Pressure Guidewire System is as safe and effective as the predicate devices.

One difference is that the portable display for predicate (K092105) is sold separately and can be only used as specified in the portable display intended use. The Zurich Pressure Guidewire System contains both the guidewire and the display therefore there is no need for a separate statement for the portable display. They can only be used together to support the intended use.

The difference in wording of the indications for use is a grammar/readability preference only; i.e. the sentences have been written for readability and preference. This grammar difference is not critical to the intended therapeutic, diagnostic, prosthetic, surgical, or other use of the device and does not affect the safety and effectiveness of the Zurich Pressure Guidewire System when used as labeled.

The comparison between the Subject Device and the predicates is presented below.

Device Characteristics	**Zurich Pressure Guidewire System**	**Predicate K131452**	**Predicate K092105**	**Comparison Result**
Product Name	Zurich Pressure Guidewire System Model 100	PressureWire Certus (interventional guidewire)	RadiAnalyzer Xpress (portable display)	___

Device Characteristics	**Zurich Pressure Guidewire System**	**Predicate K131452**	**Predicate K092105**	**Comparison Result**
Intended Use of the System (Guidewire and Display)	Zurich Pressure Guidewire System is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output of the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on temperature or pressure, e.g. Fractional Flow Reserve (FFR).	The PressureWire is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output of the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on temperature or pressure, e.g. Fractional Flow Reserve (FFR).	RadiAnalyzer® Xpress is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological and blood flow parameters based on the output from one or more electrodes, transducers or measuring devices.	Substantially equivalent to K131452. The intended use for K092105 can only be achieved by being connected to K131452. The intended use of the Zurich Pressure Guidewire System is the same as the intended use of the two predicates when used together.

Device Characteristics	**Zurich Pressure Guidewire System**	**Predicate K131452**	**Predicate K092105**	**Comparison Result**
Indications for Use	Zurich Pressure Guidewire System is indicated to measure physiological parameters in the coronary and peripheral blood vessels and in the heart. Zurich Pressure Guidewire System is also indicated to direct a catheter through a blood vessel.	PressureWire™ is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.	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®.	Substantially equivalent to K131452 but has minor difference in grammar. The indication for use for K092105 can only be achieved by being connected to K131452.
Device Classification	Class II	Class II	Class II	Same
Regulation Number Product Code	21 CFR 870.2870 21 CFR 870.1330 21 CFR 870.1425 21 CFR 870.1110 DXO, DQX DQK, DSK	21 CFR 870.2870 21 CFR 870.1330 DXO, DQX	21 CFR 870.1425 21 CFR 870.1110 DQK, DSK	Same
Regulatory Classification Name	Catheter Tip Pressure Transducer, Catheter Guide Wire, Programmable Diagnostic Computer, Blood Pressure Computer	Catheter Tip Pressure Transducer, Catheter Guide Wire,	Programmable Diagnostic Computer, Blood Pressure Computer	Same

Device Characteristics	**Zurich Pressure Guidewire System**	**Predicate K131452**	**Predicate K092105**	**Comparison Result**
System				
Sterility of Guidewire	Single use, disposable, sterile, SAL 10^{-6}	Single use, disposable, sterile SAL 10^{-6}	___	Same
Sterility of Display System	Single use, disposable, sterile, SAL 10^{-6}	___	Reusable, non-sterile	The PD in Zurich Pressure Guidewire System is single use and K092105 is a capital equipment.
Shelf Life	12 months	24 months	___	Predicate device has extended shelf life.
Total Length of Cable	40 cm Connects to sterile portable display.	210 cm Connects to non-sterile display.	___	Cord length is indicative of sterile field.
Guidewire				
Nominal Diameter	0.014" (0.36 mm)	0.014" (0.36 mm)	___	Same
Guidewire Length	180 cm	175/300 cm	___	Device length is longer than predicate for same model.
Hydrophilic Coating	Hydrophilic coating at distal end	Hydrophilic coating at distal end	___	Same
Radiopacity	Radiopaque coil	Radiopaque coil	___	Same
Tip Length	3 cm	3 cm	___	Same
Sensor	Mounted on guidewire	Mounted on guidewire	___	Same
Portable Display				
Power Source	Battery	___	Electrical main	PD is a single use device and K092105 is a capital equipment.
Pressure Range	0-300 mmHg	___	-30-300 mmHg	Predicate device range is different (-30 to 0 mmHg).

Device Characteristics	**Zurich Pressure Guidewire System**	**Predicate K131452**	**Predicate K092105**	**Comparison Result**
Electrical				
Defibrillation Proof	Type CF		Type CF	Same
Classification	Class II (2-prong power cord)	___	Class I (3-prong power cord)	Difference due to prongs.
Operating Voltage	100-240V~, 0.4A, 50/60Hz	___	100-240Vm 50-60Hz	Same
Environmental conditions				
Operating Temperature	15°C-40°C (59°F-104°F)	15°C-42°C	___	2°C difference in upper limit for the predicate.
Operating Relative Humidity	30% -75%, non-condensing at 40°C	30 - 75%	___	Same

There are other minor design differences but they do not raise different questions of safety and effectiveness. Performance data demonstrate that the Zurich Pressure Guidewire System is as safe and effective as the predicate devices. Thus, the Zurich Pressure Guidewire System is substantially equivalent.

6.9 CONCLUSION

The results of these activities demonstrate that the Zurich Pressure Guidewire System is as safe, as effective, and performs as well as the predicate devices. While there are technological differences between the subject device and the predicates, scientific data shows that the differences do not raise new questions of safety or efficacy. Therefore, the Zurich Pressure Guidewire System Model 100 and predicates, K131452 and K092105, are substantially equivalent.