February 28, 2019

St. Jude Medical (now Abbott Medical)
Ka Zoua Xiong
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K183099
Trade/Device Name: QUANTIEN™ Measurement System with Software Version 1.12.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DSK
Dated: January 29, 2019
Received: January 30, 2019

Dear Ka Zoua Xiong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 C. Browning -S5

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K183099

Device Name

QUANTIEN™ Measurement System with Software Version 1.12.1

Indications for Use *(Describe)*

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

The QUANTIEN measurement system is intended for use in the 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.

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	K183099
Date Prepared	29 January 2019
Submitter Name & Address	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 55117
Contact Person	Ka Zoua Xiong Senior Specialist, Regulatory Affairs Phone: (651) 756-3903 Fax: (877) 497-0309 Email: kazoua.xiong@abbott.com
Alternative Contact Person	Marlene Peterson Manager, Regulatory Affairs Phone: (651) 756-3268 Fax: (651) 756-3301 Email: marlene.peterson@abbott.com
Proprietary/Trade Name	QUANTIEN™ Measurement System with Software Version 1.12.1
Common/Usual Name	QUANTIEN
Product Classification Code	Product Code: DQK Subsequent Product Code: DSK
Product Regulation Number and Name	21 CFR 870.1425, Programmable diagnostic computer 21 CFR 810.1110, Blood pressure computer
Device Class	II
Predicate Device	Primary: QUANTIEN™ Measurement System (K172182), cleared 18 August 2017 Secondary: Volcano iFR® Modality (K133323), cleared 14 March 2014
Device Description	The QUANTIEN™ Measurement System is a diagnostic computer designed to record, compute, display and store data from PressureWire™ guidewire and other external transducers. The information is displayed as graphs as well as numerical values on the screen. Relevant display data includes: systolic, diastolic and mean blood pressure, heart rate, Fractional Flow Reserve (FFR), Resting Full-Cycle Ratio (RFR) index, Pd/Pa and data from ECG. Information on the display screen may also be transferred to the cathlab monitoring system or an offsite video monitor. Recorded procedures can be viewed on a PC, with application specific viewing software installed such as RadiView, for post procedural review and analysis. Quantien allows for importing of a patient work list from the hospital DICOM system, exporting of recorded measurement data to DICOM or to an external server location or portable (USB) memory device.
Indications for Use/ Intended Use	The QUANTIEN™ Measurement System is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease. The QUANTIEN™ Measurement 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.

Comparison of Subject to Predicate Device

The QUANTIEN™ Measurement System is equivalent to the QUANTIEN™ Measurement System (K172182) in terms of the intended use, indications for use, fundamental design, operational and technological characteristics (reference Table 1).

The QUANTIEN™ Measurement System is equivalent to the Philips' Volcano iFR® Modality (K133323) in terms of the pressure measurement modality for the Resting Full-Cycle Ratio index (reference Table 2).

Table 1: QUANTIEN compared to Predicate (K172182)

Features	QUANTIEN™ Measurement System (Subject Device)	QUANTIEN™ Measurement System - K172182 (Predicate Device)
Intended Use	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™ 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.
Indications for Use/ Intended Use	The QUANTIEN Measurement System is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease. QUANTIEN Measurement 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. QUANTIEN Measurement 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.
Display	Backlit LCD display	Backlit LCD display
Display Features	PressureWire™ distal (Pd) and proximal/aortic (Pa) pressure, Mean Pd and Pa, Pd/Pa, RFR and ECG	PressureWire™ distal (Pd) and proximal/aortic (Pa) pressure, Mean Pd and Pa, Pd/Pa and ECG
Graphic User Interface	Display data includes systolic, diastolic and mean blood pressure, heart rate, FFR, RFR, Pd/Pa, and ECG	Display data includes systolic, diastolic and mean blood pressure, heart rate, FFR, Pd/Pa, and ECG.
Measurement Modes	FFR and RFR	FFR

Table 2: QUANTIEN compared to Predicate (K133323)

Features	QUANTIEN™ Measurement System (Subject Device)	Volcano iFR® Modality - K133323 (Predicate Device)
Intended Use	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 Volcano s5TM/s5i/CORE/CORETM Mobile Precision Guided Therapy System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures
Indications for Use	The QUANTIEN Measurement System is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease. QUANTIEN Measurement 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 iFR® Modality of the s5/sSiCORE/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.
Relevant Display Features	RFR resting full cycle ratio	iFR instant wave free ratio

Summary on Non-Clinical Testing	Verification and Validation testing were completed to demonstrate safety and effectiveness and ensure that the subject device performs as intended. Design verification and validation included the following: • Software Verification and Validation – performed to ensure that the subject device meets requirements and functions as intended • Usability Study - performed to evaluate the usability and possible use errors that may lead to patient safety issues with the introduction of the new features on the graphical user interface

Summary of Clinical Testing

No new clinical testing was completed, nor relied upon, in support of this Traditional 510(k). However, a prospective study was performed to determine the diagnostic utility of RFR for the physiological assessment of coronary artery disease in real world patients. The results of the study showed equivalence between resting full-cycle ratio (RFR) and instantaneous wave-free ratio (iFR).

RFR-FFR Hybrid Method Result Interpretation

The following gray zone and criteria for determining positive (ischemia causing) and negative (non-ischemia causing) were used for RFR result interpretation:

- RFR < 0.86: Positive (ischemia causing)
- 0.86 ≤ RFR ≤ 0.93: Gray zone, decision will be based on FFR
  - FFR ≤ 0.8: Positive (ischemia causing)
  - FFR > 0.8: Negative (non-ischemia causing)
- RFR > 0.93: Negative (non-ischemia causing)

Summary of RFR Validation Study

The results of the prospective validation study showed comparable diagnostic accuracy, percent positive agreement, percent negative agreement, PPV, and NPV values between the RFR-FFR and iFR-FFR hybrid approaches (reference Table 3).

Table 3: Summary of RFR Validation Results

	RFR-FFR	**iFR-FFR**
Diagnostic Accuracy	93.6% [91.1%, 95.6%]	92.2% [89.5%, 94.4%]
Percent Positive Agreement	91.3% [86.9%, 94.5%]	88.8% [84.1%, 92.5%]
Percent Negative Agreement	95.8% [92.6%, 97.9%]	95.4% [92.1%, 97.6%]
PPV	95.2% [91.6%, 97.6%]	94.7% [90.9%, 97.2%]
NPV	92.3% [88.4%, 95.1%]	90.2% [86.1%, 93.5%]
Diagnostic Accuracy Outside the Grey Zone	88.5% [84.1%, 92.0%]	86.8% [82.4%, 90.4%]
Lesions free from Hyperemic Agents	55.5% [51.0%, 59.9%]	58.9% [54.4%, 63.2%]
Patients free from Hyperemic Agents	50.8% [46.0%, 55.6%]	54.3% [49.5%, 59.1%]

Statement of Equivalence

The QUANTIEN™ Measurement System with Software v1.12.1 is equivalent to the QUANTIEN™ Measurement System (K172182) in terms of the intended use, indications for use, fundamental design, operational and technological characteristics.

The QUANTIEN™ Measurement System with Software v1.12. is equivalent to the Philips' Volcano iFR® Modality (K133323) in terms of the pressure measurement modality for the Resting Full-Cycle Ratio index.