



Food and Drug Administration
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August 18, 2017

St. Jude Medical
Julie Dalquist
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K172182

Trade/Device Name: QUANTIEN™ Measurement System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DSK
Dated: July 18, 2017
Received: July 19, 2017

Dear Julie Dalquist:

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 Industry and Consumer Education (DICE) 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 Industry and Consumer Education (DICE) 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

Enclosure

Indications for Use

510(k) Number (if known)

K172182

Device Name

Quantien Measurement System

Indications for Use (Describe)

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.

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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6. 510(k) Summary

The 510(k) Summary is provided below, as required by 21 CFR 807.92(c).

510(k) Number	K172182
Date Prepared:	August 18, 2017
Submitter Name and Address:	St. Jude Medical (now part of Abbott Medical) One St. Jude Medical Dr. St. Paul, MN 55117
Contact Person:	Julie Dalquist, RAC Senior Regulatory Affairs Specialist Phone (651) 756-3501 Fax (651) 756-3298 jdalquist@sjm.com
Proprietary Name:	QUANTIEN™ Measurement System
Common/Usual Name:	Quantien
Product Classification Code:	DQK
Product Regulation Number and Name:	§870.1425, Programmable Diagnostic computer
Subsequent Code:	DSK
Product Regulation Number and Name:	§870.1110, Blood Pressure computer
Device Class:	II
Predicate Device:	QUANTIEN™ Measurement System (K123984)



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<p>Device Description:</p>	<p>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. Data includes, but is not limited to: systolic, diastolic and mean blood pressure, heart rate, Fractional Flow Reserve (FFR), Pd/Pa, and data from ECG.</p> <p>Fractional Flow Reserve (FFR) is the ratio of distal coronary arterial pressure to aortic pressure, measured during hyperemia. It provides the maximal blood flow in the presence of a stenosis as a fraction of the achievable blood flow that would exist in the hypothetical situation that the stenosis was not present. The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated. This functionality is achieved when the QUANTIEN™ Measurement System is used in conjunction with the manufacturer's distal intracoronary pressure transducer and a proximal aortic pressure transducer.</p> <p>Pd/Pa is the ratio of distal coronary arterial pressure to aortic pressure measured at resting conditions. The physician may use Pd/Pa at rest, along with knowledge of patient history, medical expertise and clinical judgment to determine if additional measurement of FFR during hyperemia or therapeutic intervention is indicated.</p> <p>Information on screen can also be transferred to an external hemodynamic recording system (HRS) or to an external video monitor. Recorded procedures can be viewed on a PC for post-procedural review and analysis with application specific viewing software installed, such as RadiView™ software.</p> <p>Additional functions let you import a patient work list from the hospital DICOM system, export recorded measurement data to DICOM or to an external server location or save it to a USB memory stick.</p>
<p>Intended Use:</p>	<p>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.</p> <p>The QUANTIEN™ system is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire™ guidewire.</p>



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<p>Comparison of Subject to Predicate Device:</p>	<p>The intended use and technological characteristics of the QUANTIEN™ Measurement System that is subject to this Special 510(k) submission are the same as the predicate, as summarized in the following table.</p>		
	<p>Character-istic</p>	<p>QUANTIEN™ Measurement System (subject device)</p>	<p>QUANTIEN™ Measurement System (predicate device)</p>
	<p>Intended Use</p>	<p>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 indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire™ guidewire.</p>	<p>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 indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire™ guidewire.</p>
	<p>Display</p>	<p>Backlit LCD</p>	<p>Backlit LCD</p>
	<p>Display Features</p>	<p>PressureWire™ distal (Pd) and proximal/aortic (Pa) pressure Mean Pd and Pa Pd/Pa ECG</p>	<p>PressureWire™ distal (Pd) and proximal/aortic (Pa) pressure Mean Pd and Pa Pd/Pa ECG</p>
<p>Summary on Non-Clinical Testing:</p>	<p>No new non-clinical testing was completed, nor relied upon, in support of this Special 510(k) submission.</p>		
<p>Summary of Clinical Testing:</p>	<p>No new clinical testing was completed in support of this Special 510(k) submission. Physician use and data analysis was completed and published publicly. Comparison to FFR was equivalent clinically, and comparison to iFR (as per the guidelines) was shown equivalent in clinical literature and publication.</p>		
<p>Statement of Equivalence:</p>	<p>The QUANTIEN™ Measurement System described in this Special 510(k) submission is substantially equivalent to the currently-marketed predicate device, based on comparisons of the device classifications, technological characteristics, and intended use.</p>		