April 30, 2022

Abbott Medical
Kenny Bello
Regulatory Affairs Project Manager
4 Robbins Road
Westford, Massachusetts 01886

Re: K220243/S001
Trade/Device Name: Ultiri™ Measurement System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DSK
Dated: January 27, 2022
Received: January 28, 2022

Dear Kenny Bello:

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 and Part 809); 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,

Aneesh Deoras
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
U.S. Food and Drug Administration

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220243

Device Name

Ultiri™ Measurement System

Indications for Use *(Describe)*

Indications for Use (Software)
The Ultreon™ Software for Ultiri™ Measurement System is intended to be used only with compatible Ultiri™ Measurement Systems.

The Ultiri™ Measurement System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

Indications for Use (capital equipment hardware)
The Ultiri™ Measurement System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

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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510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K220243
Date Prepared	March 22, 2022
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA 01886
Contact Person	Kenny M Bello 240-302-8627 kennym.bello@abbott.com
Alternative Contact Person	Jose Marquez 978-846-2640 jose.marquez1@abbott.com
Proprietary / Trade Name	Ultiri™ Measurement System
Common / Usual Name	Programmable Diagnostic Computer, Blood Pressure Computer
Product Classification	Product Code: DQK, DSK Classification Name: Computer, Diagnostic, Programmable
Product Regulation Number	21 CFR 870.1425 21 CFR 870.1110
Device Class	II
Predicate Devices	Primary Predicate: OPTIS™ Mobile Next Imaging System, Optis Integrated Next Imaging System (K210458) Secondary Predicate: QUANTIEN™ Measurement System (K183099)
Device Description	The Ultiri™ Measurement System is a diagnostic computer designed to record, compute, display and store data received wirelessly from the PressureWire™ guidewire and Wi-box. The system's main component is an all-in-one personal computer (AiO-PC) operating Ultreon™ Software for Ultiri™ Measurement System. It is compatible with the PressureWire X Guidewire and Wi-Box AO Transmitter. 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), and Resting Full-cycle Ratio (RFR). The physician may use FFR, Pd/Pa at rest and RFR parameters, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

	The Ultreon™ Software provides guided instructions for the physician to setup a physiology procedure. The display of the user interface can be output to an external video monitor. Additional functions allow the user to import patient lists from the hospital's DICOM (Digital Imaging Communications server) system, export recorded measurement data to DICOM or to an external server location or save it to a USB memory stick. Ultiri™ Measurement System is not intended for patient contact and is a non-sterile device that can be draped for sterile interaction. Ultiri™ Measurement System is distributed as a package with the following components: • All-in-One PC (with Ultreon Software) • DC power supply • AC power cords • Instructions for use • USB flash drive • Video output adapter(s) With the Ultreon™ Software application, the proposed Ultiri Measurement System is intended for use in the catheterization and related cardiovascular specialty laboratories and computes and displays physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. Resting Full-cycle Ratio (RFR), Fractional Flow Reserve (FFR), and Pd/Pa at rest physiological waveforms are also measured by the system to assess the severity of a coronary lesion by measuring the pressure drop across the lesion (distal vs proximal pressure). The physician may use the RFR or FFR parameter, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.
Indications for Use	**Indications for Use (Software)** The Ultreon™ Software for Ultiri™ Measurement System is intended to be used only with compatible Ultiri™ Measurement Systems. The Ultiri™ Measurement System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated. **Indications for Use (capital equipment hardware)** The Ultiri™ Measurement System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

	Feature	**Primary Predicate OPTIS™ Next Imaging System**	**Secondary Predicate QUANTIEN™ Measurement System**	**Proposed Device Ultiri™ Measurement System**	**Comparable Properties**

Comparison of Subject to Predicate Device	**510k**	Abbott (K210458) DQS, DSK, NQQ	Abbott (K183099) DQS, DSK	Abbott (tbd) DQS, DSK	Equivalent NQQ Imaging
	Indications for Use	OCT and physiology indications	Physiology-only indications	Physiology-only indications	Physiology-only indications. Included in the primary predicate and secondary predicate
	Software / GUI / Workflow	Ultreon Software	Quantien Software (SW Version 1.12.1)	Ultreon Software	Same as the primary predicate, OPTIS Next System
	Operating System	Windows 10	Linux Software	Windows 10	Same as the primary predicate System
	Measurement & Display Features	• Physiological parameters • OCT Image recordings	• Physiological parameters	• Physiological parameters	same as the secondary predicate System and Included in the primary predicate
	Physiology Functionality	• FFR & RFR • Pa data from an external hemodynamic • Pd receiver Thermo View • Wi-Box transmitter.	• FFR & RFR • Pa data from an external hemodynamic • Pd receiver Thermo View • Wi-Box transmitter.	• FFR & RFR • Pa data from an external hemodynamic • Pd receiver Thermo View • Wi-Box transmitter.	Same algorithms as used in the predicates. Same output Receiver as used in the primary predicate
	Data Receiver	• PressureWire X (Wireless) • PressureWire X (corded)	• PressureWire X (Wireless) • PressureWire X (corded)	• PressureWire X (Wireless)	Same Only wireless PressureWire X is supported by Ultiri Measurement System.
	Compatible devices	• PressureWire X (Wireless) • Wi-Box	Same	Same	No change
Summary of Technological Characteristics of the Subject	The proposed Ultiri™ Measurement System with Ultreon™ Software is substantially equivalent to the commercially available Abbott OPTIS™ Next Imaging Systems with Ultreon™ Software (K210458) and the Abbott QUANTIEN Measurement System (K183099).				

Device as Compared to the Predicate Devices:	The Ultiri™ Measurement System is indicated for Physiological parameters as cleared for the predicate Abbott OPTIS Next Imaging System and QUANTIEN Measurement System. The system uses the Ultreon™ Software as cleared for the Abbott OPTIS™ Next Imaging Systems. The overall system's main components include Ultiri™ Measurement System (All-in-one PC) operating Ultreon™ Software for Ultiri™ Measurement System and compatible pressure wires and Wi-box. The information is displayed as graphs as well as numerical values on the screen as used in both predicates. Like the primary predicate device, the Ultiri™ Measurement System is not intended for patient contact for the physiology workflow. Ultiri™ Measurement System is a non-sterile device that can be draped for sterile interaction. The physiological parameters, Pd/Pa at rest, RFR, and FFR, are computed by the Ultiri Measurement System using inputs from a distal intracoronary pressure transducer and a proximal aortic pressure transducer. These physiological parameters assist the physician in assessing the severity of a coronary lesion. The principles of operation of the proposed device are identical to the predicate device.
Summary of Non-Clinical Testing	Verification and Validation testing were completed to demonstrate substantial equivalence and ensure that the subject device performs as intended. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence. Design verification and validation included the following: • Software design verification testing was performed to provide objective evidence that design outputs met design inputs as defined in the software requirements documents. • A human factors summative validation was performed to demonstrate that the device could be used safely and effectively through the evaluation of critical tasks with intended users. • Hardware design verification testing was performed to provide objective evidence that design outputs met design inputs. • Packaging Validation testing was performed to demonstrate that the packaging maintains product integrity, and end user functionality, after exposure to extreme climatic conditioning and distribution/transportation simulation testing. • Design Validation testing was performed to provide objective evidence that user needs were met. • Risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. • EMC and Electrical Safety Verification was performed to evaluate against internationally recognized standards for electrical safety and electromagnetic compatibility. Testing to these standards was performed and conform to the applicable standards. • Cybersecurity Risk Assessment and Testing was completed. A comprehensive risk assessment for cybersecurity threats and vulnerabilities was performed. The assessment includes a threat model, risk analysis, traceability of control

	measures/mitigations to verification and validation testing, and a summary of cybersecurity-related instructions for use. The results of penetration testing, vulnerability scanning, static code analysis, cybersecurity bill of materials and component scanning, and other cybersecurity documentation are provided. The proposed Ultiri Measurement System was tested and found to be as safe and effective as the predicate device for intended users, uses and use environments, and met design specifications through the Abbott quality management system design control verification and validation processes.
Summary of Clinical Testing	The proposed Ultiri™ Measurement System device has the same intended use and similar technological characteristics as the predicate devices. The differences in technological characteristics were evaluated through non-clinical bench performance testing. No clinical testing was completed, nor relied upon, in support of this Traditional 510(k).
Statement of Equivalence	The proposed Ultiri™ Measurement System with Ultreon™ Software design leverages on the previously cleared Abbott predicates, Abbott OPTIS™ Next Imaging Systems with Ultreon™ Software (K210458) and the Abbott QUANTIEN ™ Measurement System (K183099). It uses the same scientific technology as the predicate devices. The differences discussed in this section does not raise different questions of safety and effectiveness. Based on the successful verification and validation testing, performance testing, conformance to standards, and development under Abbott Quality Management System, we believe that the subject device Ultiri™ Measurement System is substantially equivalent to the predicate devices.