December 17, 2019

Abbott Medical
Anita Xavier
RA Project Manager
4 Robbins Road
Westford, Massachusetts 01886

Re: K192267
Trade/Device Name: ILUMIEN System with AptiVue Software version D.3
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: November 18, 2019
Received: November 21, 2019

Dear Anita Xavier:

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,

Nicole Gillette
Acting 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)*
K192267

Device Name
ILUMIEN System with AptiVue Software version D.3

Indications for Use *(Describe)*
The ILUMIEN™ system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.
The ILUMIEN 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Paperwork Reduction Act (PRA) Staff
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510(k) Summary Per 21 CFR §807.92	
510(k) Number	K192267
Date Prepared	20 November 2019
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA 01886
Contact Person	Anita Xavier Regulatory Affairs Project Manager Phone: (408) 674 8367 Email: anita.xavier@abbott.com
Alternative Contact Person	Jose Marquez Associate Director, Regulatory Affairs Phone: (978) 577-3578 Email: jose.marquez1@abbott.com
Proprietary/Trade Name	ILUMIEN System with AptiVue Software version D.3
Common/Usual Name	ILUMIEN Systems
Product Classification Code	Product Code: NQQ
Product Regulation Number and Name	21 CFR 892.1560
Device Class	II
Predicate Device	Primary: ILUMIEN™ System (K150237), cleared 05 May 2015 Secondary: ILUMIEN™ OPTIS™, OPTIS™ Integrated, OPTIS™ Mobile (K183320), cleared 02 April 2019
Device Description	ILUMIEN™ with AptiVue™ Software (version D.3) perform Optical Coherence Tomography (OCT), Fractional Flow Reserve (FFR), and Resting Full-cycle Ratio (RFR) procedures and provide images of the coronary arteries in patients who are candidates for transluminal interventional procedures. FFR, Pd/Pa at rest, and RFR physiological waveforms measured by the system are used to assess the severity of a coronary lesion by measuring the pressure drop across the lesion (distal vs proximal pressure).
Indications for Use/ Intended Use	The ILUMIEN™ system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN 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.

Comparison of Subject to Predicate Device	ILUMIEN™ with AptiVue™ Version D.3 software is equivalent to the predicate ILUMIEN™ system (K150237) for intended use, operational characteristics, and fundamental design of the device. Changes to technological characteristics of the device do no raise different questions of safety or effectiveness. ILUMIEN™ with AptiVue™ Version D.3 software is equivalent to the OPTIS™ Systems with AptiVue™ Version E.5 Software (K183320). The tables below provide a comparison of the subject device to the primary and secondary predicate devices.

Feature	ILUMIEN Systems with version D.2 Software (Primary Predicate)	ILUMIEN™ Systems with AptiVue Software Version D.3 (Proposed)
Indications for Use	The ILUMIEN imaging system with C7 Dragonfly™ DUO or Dragonfly™ OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly™ DUO or Dragonfly™ OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ DUO or Dragonfly™ OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN imaging system will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). 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.	The ILUMIEN™ system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN 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.
Intended Use	Same as Indications for Use	The AptiVue™ D-series software is intended for use

			only with compatible ILUMIEN™ imaging systems. The ILUMIEN imaging system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.
	Measurement & Display Features	OCT recordings, Pd/Pa recordings and FFR physiological waveforms	OCT recordings, Pd/Pa at rest, FFR, and RFR physiological waveforms.
	Design Modifications	NA	Modifications to the software included the addition of a new physiological index named RFR and support for the Dragonfly OpStar catheter
	Feature	**OPTIS Systems with AptiVue Software Version E.5 (Secondary Predicate)**	**ILUMIEN™ Systems with AptiVue Software Version D.3 (Proposed)**
	Indications for Use	The OPTIS imaging system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly™ imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS imaging 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	The **ILUMIEN™** imaging system with **a** compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly™ imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The **ILUMIEN™** imaging 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

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<tr><td></td><td>therapeutic intervention is indicated.</td><td>knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.</td></tr>
<tr><td>Intended Use</td><td>The AptiVue™ E-series software is intended for use only with compatible OPTIS™ imaging systems. OPTIS™ imaging systems are intended for use in the catheterization and related cardiovascular specialty laboratories.</td><td>The AptiVue™ D-series software is intended for use only with compatible ILUMIEN™ imaging systems. The ILUMIEN imaging system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.</td></tr>
<tr><td>Measurement & Display Features</td><td>OCT recordings, Pd/Pa recordings, RFR and FFR physiological waveforms</td><td>OCT recordings, Pd/Pa recordings, RFR and FFR physiological waveforms</td></tr>
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The modifications in the proposed D.3 software version do not affect the intended use of the ILUMIEN System with AptiVue D.3 software nor do they alter the fundamental scientific technology of the system. There was no increase in existing risks with the addition of the RFR feature. The same RFR feature that was cleared under K183320 for AptiVue software version E.5 on the OPTIS systems has been implemented in the proposed AptiVue software version D.3. The device user interface, overall functionality, the RFR feature and the risks associated with the overall implementation of the RFR algorithm in the proposed D.3 software remain identical to the cleared AptiVue software version E.5.
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<tr><td>Summary on Non-Clinical Testing</td><td>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</td></tr>
<tr><td>Summary of Clinical Testing</td><td>No new clinical testing was completed, nor relied upon, in support of this Special 510(k).</td></tr>
<tr><td>Statement of Equivalence</td><td>ILUMIEN™ with AptiVue™ Version D.3 software is equivalent to the predicate ILUMIEN™ system (K150237) for intended use, operational characteristics, and fundamental design of the device. Changes to technological characteristics of the device do no raise different questions of safety or effectiveness

ILUMIEN™ with AptiVue™ Version D.3 software is equivalent to the OPTIS™ systems with AptiVue™ Version E.5 software (K183320) for the Resting Full-Cycle Ratio physiological index.</td></tr>
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