April 2, 2019

Abbott Medical
Steve Vitale
Regulatory Project Manager
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K183320
Trade/Device Name: ILUMIEN OPTIS, OPTIS Integrated, OPTIS Mobile with AptiVue Software version E.5
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: March 7, 2019
Received: March 8, 2019

Dear Steve Vitale:

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,

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)*
K183320

Device Name
ILUMIEN OPTIS, OPTIS Integrated, OPTIS Mobile with AptiVue Software version E.5

Indications for Use *(Describe)*
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 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.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K183320
Date Prepared	27 November 2018
Submitter Name & Address	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 55117
Contact Person	Steve Vitale Regulatory Affairs Specialist Phone: (651) 756-2420 Fax: (651) 756-3301 Email: steve.vitale@abbott.com
Alternative Contact Person	Marlene Peterson Senior Regulatory Affairs Manager Phone: (651) 756-3268 Fax: (651) 756-3301 Email: marlene.peterson@abbott.com
Proprietary/Trade Name	ILUMIEN OPTIS, OPTIS Integrated, OPTIS Mobile with AptiVue Software version E.5
Common/Usual Name	OPTIS or OPTIS Systems
Product Classification Code	Product Code: NQQ
Product Regulation Number and Name	21 CFR 892.1560
Device Class	II
Predicate Device	Primary: OPTIS Systems with E.4 Software (K160878), cleared 29 June 2016 Secondary: Volcano iFR® Modality (K133323), cleared 14 March 2014
Device Description	OPTIS™ with AptiVue™ Software (version E.5) 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 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 therapeutic intervention is indicated.

Comparison of Subject to Predicate Device

OPTIS™ with AptiVue™ Version E.5 software is equivalent to the predicate OPTIS™ system (K160878) 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 (see **Table 1**).

OPTIS™ with AptiVue™ Version E.5 software is equivalent to the Philips' Volcano iFR® Modality (K133323) for the Resting Full-Cycle Ratio physiological index (see **Table 2**).

Table 1: OPTIS™ compared to Predicate (K160878)

Features	OPTIS™ Systems with AptiVue™ Version E.5 Software **(Proposed Device)**	OPTIS™ Systems with version E.4 Software (K160878) **(Predicate Device)**
Intended Use	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.	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.
Indications for Use/ Intended 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 therapeutic intervention is indicated.	The OPTIS imaging system with 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 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 OPTIS 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.

Measurement & Display Features	OCT recordings, FFR, Pd/Pa at rest, and **RFR** physiological waveforms	OCT recordings, FFR and Pd/Pa at rest physiological waveforms

Table 2: OPTIS™ compared to Predicate (K133323)

Features	OPTIS™ Systems with AptiVue™ Version E.5 Software **(Proposed Device)**	Volcano iFR® Modality - K133323 **(Predicate Device)**
Intended Use	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.	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 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 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.

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>therapeutic intervention is indicated.</td><td></td></tr>
<tr><td>Relevant Display Features</td><td>RFR resting full cycle ratio</td><td>iFR instant wave free ratio</td></tr>
</table>
</td></tr>
<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 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).

<u>RFR-FFR Hybrid Method Result Interpretation</u>
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
o FFR ≤ 0.8: Positive (ischemia causing)
o FFR > 0.8: Negative (non-ischemia causing)
• RFR > 0.93: Negative (non-ischemia causing)

<u>Summary of RFR Validation Study</u>
The results of the 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
<table>
<tr><th></th><th>RFR-FFR</th><th>iFR-FFR</th></tr>
<tr><td>Diagnostic Accuracy</td><td>93.6%
[91.1%, 95.6%]</td><td>92.2%
[89.5%, 94.4%]</td></tr>
<tr><td>Percent Positive Agreement</td><td>91.3%
[86.9%, 94.5%]</td><td>88.8%
[84.1%, 92.5%]</td></tr>
<tr><td>Percent Negative Agreement</td><td>95.8%
[92.6%, 97.9%]</td><td>95.4%
[92.1%, 97.6%]</td></tr>
<tr><td>PPV</td><td>95.2%
[91.6%, 97.6%]</td><td>94.7%
[90.9%, 97.2%]</td></tr>
<tr><td>NPV</td><td>92.3%
[88.4%, 95.1%]</td><td>90.2%
[86.1%, 93.5%]</td></tr>
<tr><td>Diagnostic Accuracy Outside the Grey Zone</td><td>88.5%
[84.1%, 92.0%]</td><td>86.8%
[82.4%, 90.4%]</td></tr>
<tr><td>Lesions free from Hyperemic Agents</td><td>55.5%
[51.0%, 59.9%]</td><td>58.9%
[54.4%, 63.2%]</td></tr>
<tr><td>Patients free from Hyperemic Agents</td><td>50.8%
[46.0%, 55.6%]</td><td>54.3%
[49.5%, 59.1%]</td></tr>
</table>
</td></tr>
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Statement of Equivalence	OPTIS™ with AptiVue™ Version E.5 software is equivalent to the predicate OPTIS™ system (K160878) 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 OPTIS™ with AptiVue™ Version E.5 software is equivalent to the Philips' Volcano iFR® Modality (K133323) for the Resting Full-Cycle Ratio physiological index (see Table 2).