September 8, 2023

Abbott Medical
Derek Pike
Senior Regulatory Affairs Specialist
4 Robbins Road
Westford, Massachusetts 01886

Re: K232386
Trade/Device Name: ILUMIEN™ OPTIS™ System, OPTIS™ Integrated System, OPTIS™ Mobile System, with AptiVue™ Imaging Software version E.6
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system.
Regulatory Class: Class II
Product Code: NQQ
Dated: August 8, 2023
Received: August 9, 2023

Dear Derek Pike:

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 S. Deoras -S

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

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)*
K232386

Device Name
ILUMIEN™ OPTIS™ System, OPTIS™ Integrated System, OPTIS™ Mobile System, with AptiVue™ Imaging Software version E.6

Indications for Use *(Describe)*
The AptiVue™ E series software is intended to be used only with compatible OPTIS™ imaging systems.

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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5.0 510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K232386
Date Prepared	September 7, 2023
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA, 01886
Contact Person	Derek Pike 978-467-5880
Alternative Contact Person	Mingzi Deng 781-640-4474
Proprietary / Trade Name	ILUMIEN™ OPTIS™ System, OPTIS™ Integrated System, OPTIS™ Mobile System, with AptiVue™ Imaging Software version E.6
Common / Usual Name	Ultrasonic Pulsed Echo Imaging System
Product Classification	Product Code: NQQ
Product Regulation Number	21 CFR 892.1560
Predicate Device	ILUMIEN™ OPTIS™, OPTIS™ Integrated, OPTIS™ Mobile with AptiVue Software version E.5 (K183320), cleared April 2, 2019
Device Description	OPTIS™ Systems with AptiVue™ Imaging Software (version E.6) perform Optical Coherence Tomography (OCT), Fractional Flow Reserve (FFR), and Resting Full-cycle Ratio (RFR) procedures and provides images of the coronary arteries in patients who are candidates for transluminal interventional procedures. Version E.6 adds cloud connectivity to enable remote installation of software updates and transmission of system telemetry data.
Indications for Use / Intended Use	The AptiVue™ E series software is intended to be used only with compatible OPTIS™ imaging systems. 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

<table>
<tr><td></td><td colspan="3">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.</td></tr>
<tr><td rowspan="3">Comparison of Subject to Predicate Device</td><td colspan="3">ILUMIEN OPTIS System, OPTIS Integrated System, OPTIS Mobile System with AptiVue Imaging Software version E.6 is substantially equivalent to the predicate ILUMIEN OPTIS, OPTIS Integrated, OPTIS Mobile with AptiVue Software version E.5 (K183320) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics.</td></tr>
<tr><td>Feature</td><td>Predicate Device:
AptiVue Software version E.5 (K183320)</td><td>Proposed Device:
AptiVue Software version E.6</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>Same</td></tr>
<tr><td>Indications for Use</td><td>AptiVue™ E series software is intended to be used only with compatible OPTIS™ imaging systems.
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</td><td>Same</td></tr>
</table>

		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.	
Summary on Non-Clinical Testing	Software verification and validation tests were performed on OPTIS Systems with AptiVue E.6 Software in compliance with internal design control procedures. The results demonstrate that the AptiVue Software version E.6 meets the user needs and product specifications and is appropriate for its intended use and does not raise any new issues of safety and effectiveness.		
Summary of Clinical Testing	No clinical testing is provided in this pre-market notification.		
Statement of Equivalence	OPTIS Systems with AptiVue Imaging Software version E.6 is substantially equivalent to the predicate OPTIS Systems with AptiVue Imaging Software version E.5 (K183320) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics.		