April 24, 2026

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

Re: K253459
Trade/Device Name: OPTIS™ Mobile Next Imaging System (1014932);
OPTIS™ Integrated Next Imaging System (1014933);
Ultreon™ 3.0 Software Upgrade Kit (ULTR300001)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, DQK, DSK
Dated: April 20, 2026
Received: April 20, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARCO CANNELLA -S

for:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253459	?

Please provide the device trade name(s). ?

OPTIS Mobile Next Imaging System (1014932)
OPTIS Integrated Next Imaging System (1014933)
Ultreon 3.0 Software Upgrade Kit (ULTR300001)

Please provide your Indications for Use below. ?

Indications for Use for Ultreon 3.0 Software:
The Ultreon™ 3.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems.

The OPTIS™ Next Imaging Systems 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Next Imaging Systems are 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 OPTIS Mobile Next System:
The OPTIS™ Mobile Next 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Mobile Next 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 OPTIS Integrated Next System:
The OPTIS™ Integrated Next 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Integrated Next 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary for K253459

OPTIS Mobile Next and OPTIS Integrated Next with Ultreon 3.0 Software

510(k) Summary Per 21 CFR 807.92	
510(k) Number	K253459
Date Prepared	April 20, 2026
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA, 01886
Contact Person	Derek Pike 978-577-3595
Alternative Contact Person	Jose Marquez 978-577-3578
Proprietary / Trade Name	OPTIS™ Mobile Next Imaging System (1014932) OPTIS™ Integrated Next Imaging System (1014933) Ultreon™ 3.0 Software Upgrade Kit (ULTR300001)
Common / Usual Name	Ultrasonic pulsed echo imaging system
Product Classification	Product Code: NQQ, DQK, DSK
Product Regulation Number	21 CFR 892.1560 - Ultrasonic pulsed echo imaging system 21 CFR 870.1425 - Programmable diagnostic computer 21 CFR 870.1110 - Blood pressure computer
Predicate Device	OPTIS™ Mobile Next Imaging System, OPTIS™ Integrated Next Imaging System with Ultreon™ Software 1.0 (K210458)

Device Description:

The OPTIS™ Mobile Next is comprised of a cart-mounted personal computer, imaging engine, and power supply that are placed inside an ergonomically designed mobile cart. This system includes a keyboard, display monitors, mouse, tableside controller, and a Drive-motor and Optical Controller (DOC).

The OPTIS™ Integrated Next is comprised of a PC, imaging engine, and power supply that are housed in stationary cabinet which is located in the clinic/hospital equipment closet of

a catheter lab. The tableside controller, DOC and DOC Holster are located in the procedure room, and the keyboard, display monitor, and mouse are located in the control room.

The Ultreon™ 3.0 software application running on the OPTIS Next Systems performs Optical Coherence Tomography (OCT) imaging of coronary arteries using a compatible Dragonfly imaging catheter. Ultreon software leverages machine learning artificial intelligence capabilities, enabling automated morphology assessments, including augmented display of calcium, EEL (external elastic lamina), and lipidic plaques. Using wire-based physiology, Ultreon 3.0 supports evaluation of Resting Full-cycle Ratio (RFR), Fractional Flow Reserve (FFR), and Pd/Pa at rest physiological waveforms to assess the severity of a coronary lesion by measuring the pressure drop across the lesion (distal vs proximal pressure).

Intended Use / Indications for Use:

Ultreon 3.0 Software:

The Ultreon™ 3.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems.

The OPTIS™ Next Imaging Systems 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Next Imaging Systems are 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.

OPTIS Mobile Next System

The OPTIS™ Mobile Next 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Mobile Next 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.

OPTIS Integrated Next System

The OPTIS™ Integrated Next 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 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Integrated Next 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.

Technological Comparison to the Predicate:

The OPTIS™ Next Imaging Systems with Ultreon™ 3.0 Software are substantially equivalent to the predicate The OPTIS™ Next Imaging Systems with Ultreon™ 1.0 Software (K210458) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics. Changes to technological characteristics of the device are limited to the software only and do not raise new questions of safety or effectiveness.

	Predicate Device: OPTIS™ Next Imaging System with Ultreon™ 1.0 Software (K210458)	**Subject Device: OPTIS™ Next Imaging System with Ultreon™ 3.0 Software (K253459)**
Intended Use/Indications for Use	The OPTIS Next Imaging Systems with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the	The OPTIS™ Next Imaging Systems with a compatible Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated

	Predicate Device: OPTIS™ Next Imaging System with Ultreon™ 1.0 Software (K210458)	Subject Device: OPTIS™ Next Imaging System with Ultreon™ 3.0 Software (K253459)
	imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OPTIS Imaging Catheter or Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly OPTIS Imaging Catheter or Dragonfly OpStar 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 Next Imaging Systems 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.	in patients who are candidates for transluminal interventional procedures. The Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ 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™ Next Imaging Systems are 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.
System Overview	Personal computer, laser engine and power supply available in either cart-mounted (Mobile) or stationary (Integrated) configurations to provide a comprehensive imaging and	Same

	Predicate Device: OPTIS™ Next Imaging System with Ultreon™ 1.0 Software (K210458)	Subject Device: OPTIS™ Next Imaging System with Ultreon™ 3.0 Software (K253459)
	physiology diagnostic platform controlled by Ultreon Software.	
Measurement & Display	OCT recordings, FFR, Pd/Pa at rest, and RFR physiological waveforms	Same
Imaging and Physiology Compatibility	Dragonfly OPTIS and Dragonfly OpStar Imaging Catheters for OCT Imaging, PressureWire X Guidewire for physiology	Dragonfly OpStar Imaging Catheter for OCT Imaging, PressureWire X Guidewire for physiology.
Design Modifications	N/A	Ultreon 3.0 Software builds upon the predicate Ultreon 1. Software by adding: • AI-based automated lipid detection • AI-based enhancements for angio co-registration, lumen detection, guide catheter detection, and stent detection • Fast pullback for faster OCT image acquisition • Cloud connectivity for future software updates

Non-Clinical Testing Summary:

OPTIS Next Systems with Ultreon 3.0 Software were extensively tested in accordance with ISO 13485:2016, IEC 62304:2015, and ISO 14971:2019 to demonstrate safety and effectiveness, and to ensure that the systems perform as intended. All testing yielded passing results.

- Software Verification testing confirmed that the software meets all applicable design requirements and specifications.
- Software Validation testing confirmed that the software meets all applicable user requirements and is suitable for clinical use.
- The Human factors summative evaluation confirmed that the new software features did not introduce any user errors which could cause significant harm when the device is used as intended under anticipated use conditions.

- The Risk assessment and hazard analysis concluded that all risks are mitigated as far as possible and that the benefits of treatment outweigh any potential risks to the patient.

Machine Learning Validation Summary:

Ultreon 3.0 includes artificial intelligence algorithms which were developed using machine learning techniques. Real-world evidence was obtained from OCT case recordings of PCI cases representing a variety of disease states in multiple patients in the clinical setting. The artificial intelligence algorithms are deployed for both primary detection and post-processing as summarized below. All performance testing results met Abbott's pre-defined acceptance criteria.

Ultreon 3.0 introduces automatic lipid detection in OCT pullback images. The output of this algorithm is driven by artificial intelligence and used as an aid for OCT morphological assessments. For the lipid detection training data, four annotators were used to generate the reference standard. For the verification data, four annotators/reviewers were used to generate the reference standard, with one annotator overlapping the two groups.

Algorithm	Reference Standard Creation	Aspect Under Test	Appropriateness of Performance	Verification Performance Point Estimate (95% LCB)	Verification Test Set Description
Lipid Detection	Annotate perimeter of visible calcific plaque; reviewer modifications to region re-reviewed by original annotator for final agreement relative to annotation protocol	Lipid Plaque Arc Identification	The high performance of the lipid arc detection shows good correlation between the visible lipid plaque and the detection overlays displayed to the user on the 2D cross sections	Sensitivity: 98% (97%), n = 2,790 frames Specificity: 91% (90%), n = 10,068 frames	108 OCT pullbacks, across 108 patients.

The following algorithms use artificial intelligence components at either pre-processing or post-processing steps to confirm the output of the traditional computational algorithms. The output of these algorithms is not driven by machine learning.

Algorithm	ML Component Function	Reference Standard Creation	Aspect Under Test	Appropriateness of Performance	Verification Performance Point Estimate (95% LCB)	Verification Test Set Description
Auto Angio-Coregistration	A machine learning component is used as a pre-processing step to the angio-coregistration algorithm. It identifies the working vessel, using pre-contrast frames, to provide the hint points to the predicate angio-coregistration algorithm. The predicate algorithm responsible for angio-coregistration of the OCT lens marker to the working vessel remains the same, but when auto-coregistration succeeds, the user does not have to place the manual proximal and distal hint points.	Annotate OCT lens marker and location where lens marker crosses edges of stent; reviewer modification to object re-reviewed by original annotator for final agreement relative to annotation protocol	OCT lens marker location identification on Angio frames	There is high performance in the accuracy of the OCT lens marker detection displayed to the user on the angio frames.	95% (94%)	233 OCT pullbacks for single frame analysis (n = 5,928 Angio Frames)
			Cross frame locations identification on Angio frames	There is high performance in the accuracy of the cross frame location detection displayed to the user on the angio frames.	82% (81%)	89 OCT pullbacks for cross frame analysis (n = 3,892 Co-registered Objects)
Lumen (red frame) detection	The lumen contour detection and measurements remain the same predicate algorithm. The lumen confidence	Annotate contour of lumen-vessel boundary; reviewer modification to contour re-reviewed by original annotator for final	Correct low and high confidence lumen detection	The software has high performance in the detection of low-confidence lumen contours when	95% (95%)	118 OCT cases of real-world data (>200 frames/case); total n = 33,565 frame samples

Algorithm	ML Component Function	Reference Standard Creation	Aspect Under Test	Appropriateness of Performance	Verification Performance Point Estimate (95% LCB)	Verification Test Set Description
	scoring now utilizes a machine learning lumen detection as an input into the confidence scoring of lumen detection during post processing. The UI displays "red frames" for low confidence lumen detection frames on the Image Quality Assessment page.	agreement relative to annotation protocol	Correct high confidence lumen detections	displaying red-frames to the user on the Image Quality Assessment Page	98% (98%)	
			Limiting the incorrect high confidence lumen detections		2% (2%)	
			Limiting misclassification of lumen detections		5% (5%)	
Guide Catheter Detection	A post-processing step using machine learning outputs was introduced to reject false positive guide catheter detections in predicate algorithm.	Annotate frame of most distal tip of guide catheter; reviewer modification to frame re-reviewed by original annotator for final agreement relative to annotation protocol	Guide catheter tip detection within 1mm	The software has high performance in detecting the guide-catheter tip location within 1mm as seen in the OCT cross sections	Sensitivity: 100% (100%) Specificity: 100% (100%)	50 OCT cases of real-world data (n = 25 positive, n = 25 negative)

Algorithm	ML Component Function	Reference Standard Creation	Aspect Under Test	Appropriateness of Performance	Verification Performance Point Estimate (95% LCB)	Verification Test Set Description
Stent Detection	A post-processing step using machine learning outputs was introduced to reject false positive stented frame detections. Strut detection and following malapposition calculations remain the same as predicate device.	Annotate frame of most distal & proximal edge of stent; reviewer modification to frame re-reviewed by original annotator for final agreement relative to annotation protocol	Stented region detection accuracy	The software has high performance in detecting the stented region in OCT	Sensitivity: 100% (100%) PPV: 100% (100%)	80 OCT cases of real-world data (n= 40 positive, n = 40 negative)

The data sources for both testing and training were sourced from large multi-site core-lab initiatives; there may be some training and test data that originated from the same site. The data sets used for testing (verification) and training were independent and sequestered by the Abbott QA team.

The machine learning algorithm of the Ultreon 3.0 software demonstrated consistent and comparable performance across subgroups by vessel characteristics such as MLA and calcification as stratified by calcium score.

Conclusion:

The non-clinical data supports the safety of the device, and the verification and validation testing demonstrates that the subject device should perform as intended. Based on the totality of evidence provided in this 510(k), the subject device is substantially equivalent to the predicate.