June 8, 2021

Abbott Medical
Steve Vitale
Regulatory Affairs Project Manager
4 Robbins Road
Westford, Massachusetts 01886

Re: K210458
Trade/Device Name: OPTIS™ Mobile Next Imaging System, OPTIS™ Integrated Next Imaging System with Ultreon™ Software 1.0
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, DQK, DSK
Dated: May 6, 2021
Received: May 7, 2021

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/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
Acting Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K210458

Device Name
OPTIS™ Mobile Next Imaging System, OPTIS™ Integrated Next Imaging System with Ultreon™ Software 1.0.

Indications for Use *(Describe)*
The Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems.
The OPTIS Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the 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 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™ Mobile Next and OPTIS™ Integrated Next with a compatible Dragonfly™ OPTIS™ or Dragonfly™ OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OPTIS or Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly OPTIS 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 Mobile Next and 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.

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.

510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K210458
Date Prepared	May 6, 2021
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA, 01886
Contact Person	Steven Vitale (m) 612-214-9102 steve.vitale@abbott.com
Alternative Contact Person	Jose Marquez (m) 978-846-2640 jose.marquez1@abbott.com
Proprietary / Trade Name	OPTIS™ Mobile Next Imaging System, OPTIS™ Integrated Next Imaging System with Ultreon™ Software 1.0
Common / Usual Name	OPTIS Next
Product Classification	Product Code: NQQ
Product Regulation Number	21 CFR 892.1560 21 CFR 870.1425 21 CFR 870.1110
Device Class	II
Predicate Device	K192019: Dragonfly Opstar™ Imaging Catheter, AptiVue™ Software version E.5.1, cleared November 8, 2019
Device Description	The OPTIS™ Next Imaging System is comprised of two devices providing the same set of features: • The OPTIS™ Mobile Next Imaging System 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.

	With the Ultreon™ 1.0 software application, these systems perform Optical Coherence Tomography (OCT) imaging of coronary arteries using compatible Dragonfly imaging catheters. 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 / Intended Use	**Indications for Use (Software)** The Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems. The OPTIS Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the 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 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 OPTIS™ Mobile Next [and OPTIS™ Integrated Next] with a compatible Dragonfly™ OPTIS™ or Dragonfly™ OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OPTIS or Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly OPTIS 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 Mobile Next [and 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

<table>
<tr><td></td><td colspan="3">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">The OPTIS™ Next Imaging System with Ultreon™ Software version 1.0 is equivalent to the predicate OPTIS™ Imaging System with AptiVue™ Software version E.5.1 (K192019) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics. Changes to technological characteristics of the device do not raise new questions of safety or effectiveness.</td></tr>
<tr><td>Feature</td><td>Predicate Device:
OPTIS System with AptiVue™ Software Version E.5.1 (K192019)</td><td>Proposed Device:
OPTIS Next Imaging System with Ultreon Software version 1.0</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 Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems.</td></tr>
<tr><td>Indications for Use</td><td>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</td><td>The OPTIS Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the 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 System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further</td></tr>
</table>

		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.	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.
	Measurement & Display Features	OCT recordings, FFR, Pd/Pa at rest, and RFR physiological waveforms	OCT recordings, FFR, Pd/Pa at rest, and RFR physiological waveforms
	Design Modifications	N/A	Modifications to the Ultreon 1.0 software have been made to include automated morphology assessment of External Elastic Lamina (EEL) and calcium, display of live angiography imagery on the OPTIS Next Imaging System display monitors, and user interface guided workflows for image data acquisition and review. Software updates were made to the following existing features: • OCT image color map • OCT pullback auto-trigger • Angio co-registration • Vessel sizing • Stent analysis • Stent expansion • Cybersecurity Software design verification and validation testing have been performed which concludes these modifications demonstrate claims of substantial equivalence to the AptiVue E.5.1 software.
	Feature	**OPTIS Mobile, OPTIS Integrated Hardware (Predicate)**	**OPTIS Mobile Next, OPTIS Integrated Next Hardware (Proposed)**

	Indications for Use	The OPTIS™ mobile system [and OPTIS™ integrated 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 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 system [and OPTIS integrated 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™ Mobile Next [and OPTIS™ Integrated Next] with a compatible Dragonfly™ OPTIS™ or Dragonfly™ OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OPTIS or Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly OPTIS 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 Mobile Next [and 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.
	Design Modifications	N/A	Modifications to the OPTIS Mobile Next, OPTIS Integrated Next Hardware have been made to support of the computational speed, display, electrical compliance, and cybersecurity requirements of the system. • Graphics processing unit • Memory • Power supply • Main motherboard and CPU • Solid-state drive storage

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- Trusted Platform Module (TPM) chip supporting cybersecurity
- Ferrites added to the USB-over-Ethernet Extender Cable

Design verification and validation testing has been performed which concludes these modifications demonstrate claims of substantial equivalence to the OPTIS Mobile, OPTIS Integrated Hardware.
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<tr><td>Summary on Non-Clinical Testing</td><td colspan="3">

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
- Human Factors -Summative Usability Study – performed to demonstrate that the updated user interface, 1) does not trigger any serious harm based on use error or use problems, for the intended uses, and under the expected use conditions; and, 2) shows no pattern of use errors or problems that could result in serious harm and that could be eliminated or reduced through further modification of the user interface, device labeling, or user training.
- Hardware/System/packaging Verification – performed to demonstrate that the OPTIS Next Imaging System products and packaging meet specifications, are appropriate for their intended use, and do not raise new questions of safety or effectiveness.
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<tr><td>Summary of Clinical Testing</td><td colspan="3">

No new clinical testing was completed, nor relied upon, in support of this Traditional 510(k). However, clinical analysis of published literature was used to support a labeling change to reflect the resting full cycle ratio (RFR) cut-off of 0.89

<table>
<tr><th colspan="2">RFR Interpretation</th></tr>
<tr><th>RFR Value</th><th>Interpretation [1,2]</th></tr>
<tr><td>RFR ≤ 0.89</td><td>Indicates that a lesion is hemodynamically significant.</td></tr>
<tr><td>RFR > 0.89</td><td>Indicates that a lesion is not hemodynamically significant.</td></tr>
</table>

RFR has been validated for clinical accuracy and outcomes in over 2,500 patients [1-6]. Multiple peer-reviewed publications demonstrate the equivalence of RFR to other non-hyperemic pressure ratios (NHPR). IRIS-FFR and 3V FFR-FRIENDS studies compared all NHPRs and concluded that all have the same class effect and are broadly equivalent in terms of diagnostic and prognostic performance [3-5]. Therefore, RFR-guided treatment at a cut-off of 0.89 is equivalent to other NHPR-guided treatment.

The above RFR dichotomous cut-off of 0.89 represents a threshold for lesions indicative of hemodynamically significant. An RFR of 0.89 is, therefore, equivalent to an FFR of 0.80 as a threshold for ischemia detection.

References:

1. Svanerud et. al. Validation of a novel non-hyperaemic index of coronary artery stenosis severity: the Resting Full-cycle Ratio (**VALIDATE RFR**) study. EuroIntervention 2018; 14(7): 806-814.
2. Kumar et. al. Real world validation of the nonhyperemic index of coronary artery stenosis
</td></tr>
</table>

	severity-Resting full-cycle ratio-**RE-VALIDATE**. Catheter Cardiovasc Interv. 2020; 96(1): E53-E58. 3. Lee et. al. Physiologic and Clinical Assessment of Resting Physiologic Indices. Circulation 2019; 139:889-900. 4. Ahn J et al. Fractional Flow Reserve and Cardiac Events in Coronary Artery Disease. Circulation. 2017 Jun 6; 135(23): 2241-2251. 5. Lee et al. Clinical Outcome of Lesions with Discordant Results Among Different Invasive Physiologic Indices. Circulation J 2019; 83: 2210-2221. 6. Jeremias et al. RFR: A Novel Physiologic Index Compared to FFR.
Statement of Equivalence	As demonstrated by risk management activities, software verification, and HFE usability study testing the proposed OPTIS Next Imaging System does not raise new questions of safety or effectiveness, as compared to the predicate device, meets requirements, supports claims of substantial equivalence, and is acceptable for use. Modifications to the software of the device do no raise new questions of safety or effectiveness. As demonstrated by risk management activities, hardware/system verification, and electrical compliance testing the proposed OPTIS Next Imaging System does not raise new questions of safety or effectiveness, as compared to the predicate device, meets requirements, supports claims of substantial equivalence, and is acceptable for use. Modifications to the hardware of the device do no raise new questions of safety or effectiveness.