November 8, 2019

Abbott Medical
Richard Demello
Senior Regulatory Affairs Specialist
4 Robbins Road
Westford, Massachusetts 01886

Re: K192019
Trade/Device Name: Dragonfly OpStar™ Imaging Catheter, AptiVue™ Software version E.5.1
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, NQQ
Dated: October 4, 2019
Received: October 7, 2019

Dear Richard Demello:

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
Assistant Director (Acting)
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)*
K192019

Device Name
Dragonfly OpStar™ Imaging Catheter, AptiVue™ Software version E.5.1

Indications for Use *(Describe)*

The Dragonfly OpStar™ imaging catheter with OCT imaging system is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The 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 AptiVue™ E-series software is intended for use 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.

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5.0 510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K192019
Date Prepared	October 4, 2019
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA, 01886
Contact Person	Richard DeMello 978-577-3504
Alternative Contact Person	Jose Marquez 978-577-3578
Proprietary / Trade Name	Dragonfly OpStar™ Imaging Catheter, AptiVue™ Software version E.5.1
Common / Usual Name	Diagnostic Imaging Catheter
Product Classification	Product Code: DQO, NQQ
Product Regulation Number	21 CFR 870.1200
Predicate Device	OPTIS Integrated System, Dragonfly OPTIS™ Imaging Catheter (K141769), cleared 18 August 2014
Reference Device	ILUMIEN OPTIS, OPTIS Integrated, OPTIS Mobile with AptiVue™ Software version E.5 (K183320), cleared April 2, 2019
Device Description	The Dragonfly OpStar™ Imaging Catheter is a sterile, single-use intravascular catheter consisting of a catheter body external sheath and an internal rotating fiber optic imaging core. The external sheath serves two primary functions: 1) to facilitate placement of the device into the coronary artery and 2) to cover and protect the internal rotating fiber optic imaging core. The inner rotating fiber optic imaging core emits near infrared light to tissues and receives reflected light. It is driven by a stainless-steel torque wire visible under fluoroscopy and pulled back through the window tube of the external sheath by the Drive-motor and Optical Controller (DOC). The emitted and returned reflected light are combined and processed by the OPTIS System software to construct an OCT image. The patient is never exposed to moving parts as the external sheath completely covers the rotating imaging core. The AptiVue™ Software version E.5.1 controls the Optical Coherence Tomography (OCT) imaging engine to collect and store pressure wave form data for computing, Fractional Flow Reserve (FFR), and Resting Full-cycle Ratio (RFR) during procedures and to 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).

<table>
<tr><td>Indications for Use / Intended Use</td><td>The Dragonfly OpStar™ Imaging Catheter with OCT imaging system is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The 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.

AptiVue™ E-series software:
The AptiVue™ E-series software is intended for use 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.</td></tr>
<tr><td>Comparison of Subject to Predicate and Reference Devices</td><td>The Dragonfly OpStar Imaging Catheter is equivalent to the predicate Dragonfly OPTIS Imaging Catheter (K141769) 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.
<table>
<tr><th>Feature</th><th>Predicate Device: Dragonfly OPTIS™ Imaging Catheter (K141769)</th><th>Proposed Device: Dragonfly OpStar™ Imaging Catheter</th></tr>
<tr><td>Intended Use</td><td>The Dragonfly OPTIS™ Imaging Catheter with OCT Imaging System is intended for the Visualization and Imaging of Coronary Arteries during an interventional procedure.</td><td>The Dragonfly OpStar™ Imaging Catheter with OCT Imaging System is intended for the Visualization and Imaging of Coronary Arteries during an interventional procedure.</td></tr>
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	Indications for Use	Intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The 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.	Intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OpStar Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The 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.
	Design Modifications	N/A	Modifications are made for improved shaft support, deliverability, and reliability. These changes have been thoroughly assessed through head-to-head bench and animal testing, which conclude these modifications do not change the safety or effectiveness of the Dragonfly OpStar Imaging Catheter.
	AptiVue™ Version E.5.1 software is equivalent to the reference AptiVue™ Version E.5 Software (K183320) for intended use, operational characteristics, and fundamental design of the device. Changes to technological characteristics of the device do not raise different questions of safety or effectiveness.		
	Feature	**AptiVue™ Version E.5 Software (Reference)**	**AptiVue™ Version E.5.1 Software (Proposed)**
	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	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	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.	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.
	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 Modiciations	N/A	Modifications to the AptiVue software version E.5.1 have been made to include recognition of the Dragonfly OpStar catheter, improvements to the Angio Co-registraion feature, minor configuration changes and upgrade support. Software design verification and validation testing has been performed which concludes these modifications do not raise different questions of safety or effectiveness.

Summary on Non-Clinical Testing	Design verification and validation was performed on the Dragonfly OPSTAR Imaging Catheter as compared to the predicate Dragonfly OPTIS Imaging catheter in compliance with internal design control procedures, which included bench testing and pre-clinical animal testing. The testing involved head-to-head comparison between the proposed and predicate devices for modifications to technological characteristics. The results of this testing conclude the Dragonfly OPSTAR Imaging Catheter is substantially equivalent to the Dragonfly OPTIS Imaging Catheter. Verification and Validation testing was completed for the AptiVue software version E.5.1 to demonstrate safety and effectiveness and ensure that the subject device performs as intended. Software design verification concludes these modifications do not raise different questions of safety or effectiveness.
Summary of Clinical Testing	No clinical testing is provided in this pre-market notification.
Statement of Equivalence	The Dragonfly OpStar Imaging Catheter is equivalent to the predicate Dragonfly OPTIS Imaging Catheter (K141769) in terms of operational and technological features, hardware components, operational use and target population. Changes to technological characteristics of the device do not raise new questions of safety or effectiveness.