April 14, 2023

Abbott Medical
Mingzi Deng
Associate Director, Regulatory Affairs
4 Robbins Road
Westford, Massachusetts 01886

Re: K230411
Trade/Device Name: Dragonfly OpStar™ Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: February 14, 2023
Received: February 15, 2023

Dear Mingzi Deng:

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 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)*
K230411

Device Name
Dragonfly OpStar™ Imaging Catheter

Indications for Use *(Describe)*
The Dragonfly OpStar™ Imaging Catheter with the 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.

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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510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K230411
Date Prepared	February 14, 2023
Submitter Name & Address	Abbott Medical 4 Robbins Road Westford, MA, 01886
Contact Person	Derek Pike 978-577-3595
Alternative Contact Person	Mingzi Deng 781-640-4474
Proprietary / Trade Name	Dragonfly OpStar™ Imaging Catheter
Common / Usual Name	Diagnostic Imaging Catheter
Product Classification	Product Code: DQO
Product Regulation Number	21 CFR 870.1200
Predicate Device	Dragonfly OpStar™ Imaging Catheter, AptiVue™ Software version E.5.1 (K192019), cleared 11 November 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 Optical Coherence Tomography (OCT) image. The patient is never exposed to moving parts as the external sheath completely covers the rotating imaging core.
Indications for Use / Intended Use	The Dragonfly OpStar™ Imaging Catheter with the 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.

<table>
<tr><td rowspan="3">Comparison of Subject to Predicate Device</td><td colspan="3">The Dragonfly OpStar Imaging Catheter is substantially equivalent to the predicate Dragonfly OpStar Imaging Catheter (K192019) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics. There are no technological differences between the predicate device and new device.</td></tr>
<tr><td>Feature</td><td>Predicate Device: Dragonfly OpStar Imaging Catheter (K192019)</td><td>Proposed Device: Dragonfly OpStar Imaging Catheter</td></tr>
<tr><td>Intended Use</td><td>The Dragonfly OpStar Imaging Catheter with the OCT imaging system is intended for the visualization and imaging of coronary arteries during an interventional procedure.</td><td>Same</td></tr>
<tr><td></td><td>Indications for Use</td><td>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.</td><td>Same</td></tr>
<tr><td>Summary on Non-Clinical Testing</td><td colspan="3">Design verification and validation bench tests were performed on the Dragonfly OpStar Imaging Catheter in compliance with internal design control procedures. The results demonstrate that the Dragonfly OpStar Imaging Catheter 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.</td></tr>
<tr><td>Summary of Clinical Testing</td><td colspan="3">No clinical testing is provided in this pre-market notification.</td></tr>
<tr><td>Statement of Equivalence</td><td colspan="3">The Dragonfly OpStar Imaging Catheter is substantially equivalent to the predicate Dragonfly OpStar Imaging Catheter (K192019) in terms of intended use, indications for use, operational characteristics, fundamental design, and technological characteristics.</td></tr>
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