June 17, 2025

Terumo Corporation
℅ Patrick McDonald
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K250751
Trade/Device Name: DualView Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, OBJ
Dated: June 17, 2025
Received: June 17, 2025

Dear Patrick McDonald:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250751

Device Name

DualView Catheter

Indications for Use *(Describe)*

DualView Catheter is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

A. SUBMITTER INFORMATION (807.92(a)(1))

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Date prepared: 17JUL2025

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	DualView Catheter
Common Name:	Diagnostic Catheter
Classification Name:	Diagnostic Intravascular Catheter
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1200
Classification Product Codes:	DQO
Subsequent Product Code:	OBJ
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed devices to which substantial equivalence is claimed are:

Primary Predicate	K141769	Optis Integrated System, Dragonfly Optis Imaging Catheter
Secondary Predicate	K123621	Opticross 40 MHz Coronary Imaging Catheter

D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) for DualView Catheter is being submitted as this is a new medical device for the US market.

E. DEVICE DESCRIPTION (807.92(a)(4))

The DualView Catheter is a catheter consisting of two assemblies: the catheter sheath and the imaging core (consisting of lens and transducer). During imaging, the imaging core rotates inside the catheter sheath to obtain a 360°image of the surface layer of the vessel wall by irradiating with near-infrared light and ultrasound. By pulling back the imaging core inside the catheter sheath, an image in the long axis direction can be obtained.

This is a rapid exchange (RX) design (short monorail) catheter, which is used with a 0.014” (0.36 mm) guidewire. The catheter is 2.6 Fr (0.86 mm) in the imaging

window section and 3.0 Fr (1.01 mm) in the shaft section with an effective length of 137 cm. The catheter has a 100 cm hydrophilic coating starting from the distal end, which becomes highly lubricious when wet. The catheter has a telescoping section, and the telescoping length is 155 mm. When connected to the OPUSWAVE, the imaging core can be pulled back 150 mm in the catheter sheath.

There are two radiopaque markers. The distal radiopaque marker is located 7 mm from the distal end of the catheter sheath, and the sensor radiopaque marker is located where the near-infrared light and ultrasound are emitted. Those markers allow a user to confirm the positional relationship between the distal end of the catheter and the sensor position (imaging point). There are two depth markers, one at 90 cm and the other at 100 cm from the distal end of the catheter sheath, which serves as a guide for insertion.

The transducer has an IPX7 ingress rating in accordance with IEC 60529.

The catheter is stored in the holder tube and is secured to the catheter holder.

The catheter comes with the Motor Drive Unit (MDU) Cover and accessories. The MDU Cover consists of an adapter and a plastic cover sheet to maintain the sterility of the catheter and clean field. The catheter accessories consist of a connection tube with a three-way stopcock, a priming syringe, and a reservoir syringe for priming the catheter lumen with heparinized saline solution.

F. INDICATIONS FOR USE (807.92(a)(5))

DualView Catheter is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

DualView Catheter, the subject of this Traditional 510(k), is substantially equivalent in its Intended Use, Indications for Use, and Technological Characteristics to the predicates, Optis Integrated System, Dragonfly Optis Imaging Catheter (K141769) manufactured by LightLab Imaging Inc and Opticross 40 MHz Coronary Imaging Catheter (K123621) manufactured by Boston Scientific Corporation.

The comparison of the technological characteristics is summarized in **Table 1.**

Table 1: Summary of Comparative Information

Device Characteristics	Subject Device: DualView Catheter	Primary Predicate Device: Optis Integrated System, Dragonfly Optis Imaging Catheter (K141769)	Secondary Predicate Device: Opticross 40 MHz Coronary Imaging Catheter (K123621)
Manufacturer	Ashitaka Factory of Terumo Corporation	LightLab Imaging Inc	Boston Scientific Corporation
Intended Use	DualView Catheter is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	Same	Same
Indications for Use	DualView Catheter is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	The OPTIS Integrated System with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or 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. The OPTIS Integrated	This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

		System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.	
Imaging Energy	Optical Coherence Tomography/ Ultrasound	Optical Coherence Tomography	Ultrasound
Optical Wavelength	1300 nm	1305 nm	Not applicable
Ultrasound Frequency	40 MHz	Not applicable	40 MHz
Effective Length	1370 mm	1350 mm	1350 mm
Catheter O.D.	Imaging window: 2.6 Fr (0.86 mm) Proximal shaft: 3.0 Fr (1.01 mm)	Imaging window: 2.7 Fr Proximal shaft: 3.2 Fr	Imaging window: 2.6 Fr Proximal shaft: 3.0 Fr (1.00 mm)
Maximum guidewire O.D.	0.014” (0.36mm)	0.014” (0.356mm)	0.014” (0.36mm)
Package	Individual package on which the product label and the peel-off labels are attached 1 unit per package.	Individual package on which the product label and the peel-off labels are attached 1 unit per package.	Individual package on which the product label and the peel-off labels are attached 1 unit per package.
Operation Principle	Manual	Manual	Manual

Sterilization	Ethylene oxide	Ethylene Oxide	Irradiation
Shelf life	36 Months	24 Months	12 Months

H. NON CLINICAL TESTS (807.92(b)(1))

Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

Test Item
Radio-detectability
Appearance of Catheter
Corrosion Resistance
Tensile Strength
Freedom from leakage
Small bore connector
Sliding resistance (Imaging window)
Particle count
Slidability of Guidewire
Bending strength
Dimensions
Imaging quality
Pullback/forward durability
Coating Integrity
Stent crossability
Simulated use – Human factor usability engineering

System level Design verification and validation testing were performed on the OPUSWAVE (K250684) with the DualView Catheter to demonstrate that the product specifications met the predefined requirements and it is safe and effective for its intended use. The result of this testing concludes that the DualView Catheter is safe and effective for its intended use.

Software Verification and Validation Testing

Software verification and validation testing were conducted per IEC 62304 Standard and 'Enhanced' level of documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Content of Premarket Submissions for Device Software Functions," with OPUSWAVE (K250684)

Electrical Safety and Electromagnetic Compatibility (EMC) and Collateral Standards

Electrical safety and EMC testing was conducted for the OPUSWAVE. The system is in compliance with IEC 60601-1 and collateral standards, IEC 60601-2-18, IEC 60601-1-2, IEC 60825, and IEC 60601-2-37.

Animal Study

A safety animal study, in swine model, evaluated the tissue injury level and thrombus formation of coronary arteries that were exposed to simultaneous near-infrared light and ultrasound energy application. It was concluded that there were no issues related to tissue damage and thrombus formation in coronary arteries caused by simultaneous application or near infrared light and ultrasound.

A performance animal study, in swine model, successfully assessed key performance and handling criteria compared to predicate devices and concluded that the system performed as intended.

Biocompatibility

In accordance with ISO 10993-1, DualView Catheter is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the device is biocompatible throughout the shelf-life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014/Amd 1:2018, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices,* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, DualView Catheter, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicates, Optis Integrated System, Dragonfly Optis Imaging Catheter (K141769) manufactured by LightLab Imaging Inc and Opticross 40 MHz Coronary Imaging Catheter (K123621) manufactured by Boston Scientific Corporation.