January 16, 2025

Opsens Inc.
Dany Simard
Regulatory Affairs Specialist
750, Boulevard du Parc Technologique
Quebec, QC G1P 4S3
Canada

Re: K251367
Trade/Device Name: OptoMonitor 3
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: April 30, 2025
Received: May 1, 2025

Dear Dany Simard:

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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
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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.

510(k) Number *(if known)*
K251367

Device Name
OptoMonitor 3

Indications for Use *(Describe)*
The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during structural heart 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.

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510(K) SUMMARY OPTOMONITOR 3

SUBMITTER

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Date Prepared: January 15th, 2026

DEVICE

Name of Device: OptoMonitor 3

Regulation Number: 21 CFR 870.2870

Regulation Name: Catheter Tip Pressure Transducer

Regulatory Class: II

Product Code: DXO

PREDICATE DEVICE

The proposed OptoMonitor 3 is substantially equivalent to the OptoMonitor 3 cleared in K241418 on 02/12/2025 [Predicate].

The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION

The OptoMonitor 3 with Display Unit Software update to v1.3.0 and Capture Unit when compared to the OptoMonitor 3 cleared under K241418 includes the following changes:

New PhysioVU Software Functionality:

The PhysioVU functionality added to the OptoMonitor 3 provides a feature designed to support the cardiologist PCI workflow by displaying a time-synchronized playback of angiogram and coronary physiological pullback values such as Pd/Pa or dPR. This feature can be utilized on angiography systems

compatible with PhysioVU requirements. The validation of PhysioVU's compatibility and overall latency performance was evaluated on three representative angiography systems at 7.5 fps and 15 fps.

dPR Pullback:
A dPR Pullback display optimization has been incorporated to meet the time-synchronization requirements of PhysioVU functionality and is called Pullback 2. Pullback 2 provides an adequate delay between the angiography image and the dPR calculation and can be used as a standalone or a PhysioVU pullback.

New Capture Unit (Hardware):
The Capture Unit component is optional but required for the PhysioVU functionality. The Capture Unit is used to capture angiography images that are sent to the Display Unit. This enables the Display Unit to subsequently replay recordings of these angiograms synchronized with physiological pullback values such as Pd/Pa or dPR.

INDICATIONS FOR USE

The Indications for Use of the subject device OptoMonitor 3 remains unchanged from that of the current device cleared via K241418.

Indications for Use: The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during structural heart procedures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor 3 is substantially equivalent to the approved OptoMonitor 3 cleared via K241418, as it has the same intended use, similar technological characteristics and performance data as the subject device, OptoMonitor 3.

No new questions of safety and effectiveness were identified during the execution of Verification and Validation activities.

Therefore, the proposed device, OptoMonitor 3 meets substantial equivalence requirements with regards to the legally marketed predicate.

For detailed comparison, refer to **Table 1** on the following pages.

Table 1: OptoMonitor 3 Substantial Equivalence Table

		OptoMonitor 3 (Subject Device)	OptoMonitor 3 (Predicate)	Explanation of Variation
Regulatory Infor	Device Name	OptoMonitor 3	OptoMonitor 3	N/A
	510(k)#	K251367	K241418	N/A

		OptoMonitor 3 (Subject Device)	OptoMonitor 3 (Predicate)	Explanation of Variation
	Product Code	DXO	DXO	Same.
	Class	2	2	Same.
	Regulation Number	870.2870	870.2870	Same.
	Regulation Generic Name	transducer, pressure, catheter tip	transducer, pressure, catheter tip	Same.
Intended use	Indications for Use	The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during transcatheter aortic valve procedures.	The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during transcatheter aortic valve procedures.	Same.
	Prescription Use	Rx Only	Rx Only	Same.
Technological Characteristics	System Components / device materials	Reusable signal processor / monitor / capture unit / Embedded software Connecting cables	Reusable signal processor / monitor Embedded software Connecting cables	Equivalent. The video capture unit allows angiography video acquisition for replay of the pullback angiography sequence with the corresponding index value curve on the OptoMonitor 3. There is no impact on safety and effectiveness, intended use and performance of the device.
	System Capabilities	Measurement of intravascular blood pressure including FFR, measurement inside left ventricle and display of multiple physiological parameters, video acquisition and playback of angiography	Measurement of intravascular blood pressure including FFR, measurement inside left ventricle and display of multiple physiological parameters	Equivalent. The video capture unit allows angiography video acquisition for replay of the pullback angiography sequence with the corresponding index value curve on the OptoMonitor 3. There is no impact on safety and effectiveness,

		OptoMonitor 3 (Subject Device)	OptoMonitor 3 (Predicate)	Explanation of Variation
				intended use and performance of the device.
	Pressure Sensing & Signal Transmission Technology	Fiberoptic sensor & fiber bundle embedded in guidewire. Monitor Senses pressure from Fiberoptic sensor.	Fiberoptic sensor & fiber bundle embedded in guidewire. Monitor Senses pressure from Fiberoptic sensor.	Same.
	Operating Temperature (Monitor)	15°C to 30°C	15°C to 30°C	Same.
	Transport Temperature (Monitor)	-25°C to 60°C	-25°C to 60°C	Same.
	Operating Relative Humidity (Monitor)	10% to 85% non-condensing	10% to 85% non-condensing	Same.
	Storage Temperature (Monitor)	Room Temperature	Room Temperature	Same.
	Operating Pressure	70 to 106 kPa	70 to 106 kPa	Same.
	Pressure Range	-30 to 300 mmHg	-30 to 300 mmHg	Same.
	Pressure Accuracy	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	Same.
	Thermal Zero Shift	<0.3 mmHg/deg C	<0.3 mmHg/deg C	Same.
	Zero Drift	<1 mmHg/h	<1 mmHg/h	Same.
	Electrical Isolation	Class 2 (double isolation)	Class 2 (double isolation)	Same.
	User Interface	Touchscreen Control room: yes	Touchscreen Control room: yes	Same.
	Auto-zeroing	Yes	Yes	Same.
	Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, pressure wire instantaneous pressure, distal mean pressure	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	Same.

		OptoMonitor 3 (Subject Device)	OptoMonitor 3 (Predicate)	Explanation of Variation
	Real Time Numerical Values	Mean aortic pressure, mean pressure wire pressure, mean Pd/mean Pa; FFR, dPR. Averaged pulse rate, systolic/diastolic values, gradients, left ventricular end of diastole pressure, ARi and TIARi values	Mean aortic pressure, mean pressure wire pressure, mean Pd/mean Pa; FFR, dPR. Averaged pulse rate, systolic/diastolic values, gradients, left ventricular end of diastole pressure, ARi and TIARi values	Same.
	Recording Values	Instantaneous Pa, pressure wire and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR, pulse rate, systolic/diastolic values, ARi and TIARi values	Instantaneous Pa, pressure wire and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR, pulse rate, systolic/diastolic values, ARi and TIARi values	Same
	Display Monitor	LCD	LCD	Same.
	Aortic Input	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)	Same.
	Pressure wire Input	OptoWire™ (optical) and SavvyWire™ (optical)	OptoWire™ (optical) and SavvyWire™ (optical)	Same.
	AUX Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)	Same.
	Distal pressure output	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)	Same.
	Hardware components	Optical Unit (OU) including Signal Conditioner Unit (SCU), the Display Unit (DU) the Handle Unit (HU) and accessories (cables, power supply, the Capture Unit, etc.)	Optical Unit (OU) including Signal Conditioner Unit (SCU), the Display Unit (DU), the Handle Unit (HU) and accessories (cables, power supply, etc.)	Equivalent.
	Connected devices	OptoWire™ SavvyWire™	OptoWire™ SavvyWire™	Same.

PERFORMANCE DATA

Software Verification and Validation Testing

Non-clinical performance testing has been performed on the OptoMonitor 3 system and demonstrated compliance with the following International and FDA-recognized consensus standards in-line with FDA guidance documents: IEC 62304:2006/AMD1:2015 Medical device software – Software life cycle processes.

Software Verification and Validation activities were carried out to confirm proper operation of the device's software. Bench testing was conducted to assess the device's functionality and reliability under typical usage conditions, ensuring it meets all specified performance criteria.

Synchronization performance testing was conducted to provide evidence of accurate temporal registration of the pressure and image signals during clinical use. The intrinsic latency of the OptoMonitor 3 system was characterized by using an artificial heart bench test . Tests in Cathlab were also performed to evaluate the end-to-end latency in real environments (i.e. interfacing with real angiographic system).

In addition to these synchronization validations, other parameters were also verified including::

- Images quality
- Images acquisitions frame rate and resolutions
- System ambient temperature testing
- Pressure display synchronization
- Activation keys management
- Graphical User Interface

Regression tests were performed to confirm that previous functionalities were still operating as intended.

Usability testing was performed to verify user satisfaction and ease of use.

All tests executed demonstrated compliant results to acceptance criteria defined in the respective test plans and protocols.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was also performed to verify that the device meets all applicable electrical and safety requirements, IEC 60601-1:2020 Edition 3.2 and IEC 60601-1-2:2020 Edition 4.1, providing assurance that it operates safely in clinical environments.

The OptoMonitor 3 is shown to be at least as safe and effective as the predicate device and the inherent risks are believed to be overcome by the benefits of the device use as indicated. Therefore, all residual risks post-mitigation have been deemed acceptable for this design.

No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

All acceptance criteria were met regarding risks and device functionality.

CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the OptoMonitor 3 is comparable to the predicate, supports the substantial equivalence of the device that is the subject of this 510(k), and ensures the subject device can perform in a manner equivalent to the predicate device with the same intended use cleared via K241418.