February 12, 2025

Opsens Inc.
Marc Chaunet
Regulatory Affairs Director
750, Boulevard du Parc Technologique
Quebec, QC G1P 4S3
Canada

Re: K241418
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: January 10, 2025
Received: January 13, 2025

Dear Marc Chaunet:

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,

for Robert T. Kazmierski -S

LCDR Stephen Browning
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)*
K241418

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 OPTOMONITOR 3

SUBMITTER

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Contact Person: Marc Chaunet, Senior Regulatory Affairs Manager

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Date Prepared: January 10th, 2025

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 Opsens existing OptoMonitor 3 cleared in K213854 on 09/14/2022 [Predicate].

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

DEVICE DESCRIPTION

The proposed OptoMonitor 3 includes the display of ARi/TIARi adjunctive hemodynamic indicators when compared to the approved OptoMonitor 3 with a fully integrated TAVI software update cleared via K213854.

INDICATIONS FOR USE

The Indications for Use of the **subject** device OptoMonitor 3 remains unchanged from that of the current device cleared via K213854.

OptoMonitor 3: 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor 3 with display of ARi/TIARi adjunctive hemodynamic indicators is substantially equivalent to the approved OptoMonitor 3 cleared via K213854. The indications for use remain unchanged from the currently marketed OptoMonitor 3 indications.

The technological characteristics related to the proposed device are the same. No new questions of safety and effectiveness were identified during the execution of Verification and Validation activities.

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

For detailed comparison, refer to the Substantial Equivalence table on the following pages.

Table 1: OptoMonitor 3 with display of ARi/TIARi adjunctive hemodynamic indicators

OptoMonitor 3 with display of ARi/TIARi adjunctive hemodynamic indicators			
		OptoMonitor 3 (with ARi/TIARi)	**OptoMonitor 3 (Predicate)**
Regulatory Information	Device Name	OptoMonitor 3	OptoMonitor 3
	510(k)#	K241418	K213854
	Product Code	DXO	DXO
	Class	2	2
	Regulation Number	870.2870	870.2870
	Regulation Generic Name	transducer, pressure, catheter tip	transducer, pressure, catheter tip
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.
	Prescription Use	Rx Only	Rx Only
Technolog	System Components / device materials	Reusable signal processor / monitor Embedded software	Reusable signal processor / monitor Embedded software

OptoMonitor 3 with display of ARi/TIARi adjunctive hemodynamic indicators			
		OptoMonitor 3 (with ARi/TIARi)	**OptoMonitor 3 (Predicate)**
		Connecting cables	Connecting cables
	System Capabilities	Measurement of intravascular blood pressure including FFR and measurement inside left ventricle	Measurement of intravascular blood pressure including FFR and measurement inside left ventricle
	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.
	Operating Temperature (Monitor)	15°C to 30°C	15°C to 30°C
	Transport Temperature (Monitor)	-25°C to 60°C	-25°C to 60°C
	Operating Relative Humidity (Monitor)	10% to 85% non-condensing	10% to 85% non-condensing
	Storage Temperature (Monitor)	Room Temperature	Room Temperature
	Operating Pressure	70 to 106 kPa	70 to 106 kPa
	Pressure Range	-30 to 300 mmHg	-30 to 300 mmHg
	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)
	Thermal Zero Shift	<0.3 mmHg/deg C	<0.3 mmHg/deg C
	Zero Drift	<1 mmHg/h	<1 mmHg/h
	Electrical Isolation	Class 2 (double isolation)	Class 2 (double isolation)
	User Interface	Touchscreen Control room: yes	Touchscreen Control room: yes
	Auto-zeroing	Yes	Yes
	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
	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

OptoMonitor 3 with display of ARi/TIARi adjunctive hemodynamic indicators			
		OptoMonitor 3 (with ARi/TIARi)	**OptoMonitor 3 (Predicate)**
	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
	Display Monitor	LCD	LCD
	Aortic Input	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)
	Pressure wire Input	OptoWire™ (optical) and SavvyWire™ (optical)	OptoWire™ (optical) and SavvyWire™ (optical)
	AUX Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)
	Distal pressure output	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)
	Hardware components	Signal Conditioner Unit (SCU), the Display Unit (DU), The Handle Unit (HU) and accessories (cables, power supply, etc)	Signal Conditioner Unit (SCU), the Display Unit (DU), The Handle Unit (HU) and accessories (cables, power supply, etc)
	Connected devices	OptoWire™ SavvyWire™	OptoWire™ SavvyWire™

PERFORMANCE DATA

Risk Based Approach

The Risk Management File for the OptoMonitor 3 currently marketed in USA and cleared in K213854 has been reviewed. One risk of "indices measured under suboptimal conditions" has been identified, added to the Risk Management File and evaluated as tolerable, with benefits outweighing the risk. Other risks related to the display of the ARi/TIARi adjunctive hemodynamic indicators were already addressed in the Risk Management File as this feature is offered on the version of the device already marketed outside USA.

Risk Management documentation as well as all testing associated with the OptoMonitor 3 with TAVI are included in the software risk management file as the OptoMonitor 3 device is a currently marketed device and the only changes are software related (display of ARi/TIARi adjunctive hemodynamic indicators).

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.

Retrospective Analysis

A retrospective analysis was conducted with the objective to compare ARi and TIARi calculation of OpM3 TAVI algorithm and Microsoft Excel based on the mathematical expressions given in the literature by Sinning et al. and Bugan and Kumar et al.. The analysis data set utilized clinically derived data recorded

with the OptoMonitor from existing pre and post market data sources. A total of 30 pressure recordings from 10 unique patients, for a total of 150 beats, was analyzed.

The results of the analysis showed that manual calculation of regurgitation indices using mathematical formulas given in the literature yields statistically equivalent results to the indices displayed by OpM3 TAVI. The correlation coefficients and the graphs with the estimated line from the Deming regression, as well as the Bland-Altman plots, indicate high levels of agreement for each of the four indices. For additional exploration, the Pearson correlations were found to be higher than 0.99 for all four indices.

Clinical Study

An annotation study was retrospectively conducted on 420 waveforms in 29 patients in order to compare the values annotated by expert clinicians, a commercially available hemodynamic software and the outputs of OpM3. The experts panel annotated the systolic LV, systolic Ao, diastolic LV, diastolic Ao, and LVEDP pressures on the pressure tracings. A statistical analysis included least mean square analysis and Bland-Altman. Table 2 below shows the levels of agreement (LoA) found through Bland-Altman analysis between the values identified by the OptoMonitor 3 and by the experts panel for each of the annotation.

Table 2: Levels of Agreement (LoA) between the values identified by the OptoMonitor 3 and by the experts panel

	Upper LoA	Lower LoA
Systolic LV	0.22	-0.26
Systolic Ao	0.15	-0.17
Diastolic Ao	0.23	-0.11
Diastolic Lv	4.02	-3.45
LVEDP	4.77	-2.42

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.

The results of the verification/validation tests and the risk analysis have demonstrated that displaying of the ARi/TIARi adjunctive hemodynamic indicators to the OptoMonitor 3 with TAVI does not raise any new questions of safety and efficacy and is therefore substantially equivalent to the legally marketed predicate device the OptoMonitor 3 cleared via K213854.