June 18, 2020

Opsens Inc.
Marc Chaunet
Director, Regulatory Affairs and Quality System
750 boulevard Du Parc Technologique
Quebec, G1P 4S3 Ca

Re: K193620
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: May 18, 2020
Received: May 18, 2020

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 (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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193620

Device Name
OptoMonitor 3

Indications for Use *(Describe)*

To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/ or any interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel desease.

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."

5 510(K) SUMMARY OPTOMONITOR 3

1. SUBMITTER

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Contact Person: Marc Chaunet, Regulatory Affairs and Quality System Director

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Date Prepared: June 17, 2020

2. DEVICE

Name of Device: OptoMonitor 3

Common or Usual Name: Pressure Monitor

Classification name: Transducer, pressure, catheter tip (870.2870)

Regulatory Class: II

Product Code: DXO

3. PREDICATE DEVICE

OptoMonitor System cleared via K192340 (cleared on 12/12/2019). This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The proposed OptoMonitor 3 is a new version of the OptoMonitor System. This device and its components are considered accessories to Opsens OptoWire™ pressure guidewires and are intended for use with legally marketed pressure guidewires.

The proposed OptoMonitor 3 includes an Optical Unit (OU), a Display Unit (DU), a Handle Unit (HU) and accessories (cables, power supply, etc). These hardware components and device functionalities are equivalent to that of the previous generation OptoMonitor (K192340 (cleared on 12/12/2019).

The device is a non-sterile, non-patient contact device.

5. INDICATIONS FOR USE

The OptoMonitor 3, in conjunction with the OptoWire™ pressure guidewire, is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor 3 is substantially equivalent to the OptoMonitor cleared via K192340 on 12/12/2019.

The proposed OptoMonitor 3 is a new version of the predecessor OptoMonitor.

Indications for Use for the OptoMonitor 3 are the same as the predicate device indications K192340 (cleared on 12/12/2019).

The technological characteristics of the proposed OptoMonitor 3 are essentially the same as for the OptoMonitor. The main difference between the subject device and its predecessor resides in the following:

OPTICAL UNIT

- New casing
- New CPU and PCBs. A new software was also validated for the OU. Although, algorithms used for the FFR calculation remained unchanged from the predicate OptoMonitor.
- Addition of possibility to receive aortic pressure signal (Pa) from a Cathlab Hemodynamic system
- Addition of a low-level signal input (Aortic In) allowing to connect an aortic pressure transducer and pass-through to Cathlab Hemodynamic system
- Handle unit redesigned and connector split to separate electrical and optical connections
- Software modifications to support new hardware
- Removal of printer

DISPLAY UNIT

- Use of commercially available all-in-one PC.
- New software to support additional hardware options
- Addition of possibility to connect to hospital DICOM system

The changes have been evaluated through the Risk Management Process and no new questions of safety and effectiveness were identified. Existing questions of safety and effectiveness are valid for the proposed device. Any change raises a question concerning whether its performance can be expected to be equivalent with the predicate. Performance testing has confirmed equivalence. 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 OptoMonitor (K192340 cleared on 12/12/2019).

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

Substantial Equivalence Table				
		Proposed Device	**Predicate Device**	**Differences**
Regulatory Information	Name	OptoMonitor 3	OptoMonitor	N/A
	510(k)#	K193620	K192340	N/A
	Predicates	K192340	K173860 K142598 K111395 K041134	N/A
	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	Regulation Intended Use	Accessory equipment for processing mechanical or electrical property changes in relation to changes in blood pressure.	Accessory equipment for processing mechanical or electrical property changes in relation to changes in blood pressure.	Same
	Indications	To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	Same
Technological Characteristics	Prescription Use	Rx Only	Rx Only	Same
	System Components	Sterile, disposable guidewire Reusable signal processor / monitor Embedded software Connecting cables	Sterile, disposable guidewire Reusable signal processor / monitor Embedded software Connecting cables	Same
	System Capabilities	Measurement of intravascular blood Pressure including FFR.	Measurement of intravascular blood pressure including FFR.	Same
	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

Substantial Equivalence Table				
		Proposed Device	**Predicate Device**	**Differences**
	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	Touchscreen	Same
	Auto-zeroing	Yes	Yes	Same
	Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	Same
	Real Time Numerical Values	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa; FFR, dPR	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa; FFR, dPR	Same
	Recording Values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR	Same
	Display Monitor	LCD	LCD	Same
	Aortic Input	Low Level (5µV/V/mmHg)	High Level (100 mmHg/V)	Low level attributed to Aortic input for OpM3
	Distal Input	OptoWire (optical)	OptoWire (optical)	Same
	AUX Input	High Level (100 mmHg/V)	N/A	High level input added to AUX In for OpM3
	Distal pressure output	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)	Same
	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)	Same
	Connected devices	OptoWire™	OptoWire™	Same

7. PERFORMANCE DATA

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

Electrical safety and electromagnetic compatibility (EMC) was assessed with respect to the software change and the system was found to comply with IEC 60601-1, and IEC 60601-1-2 standard for EMC.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

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

No animal studies or clinical investigations are included with this submission.

8. CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the proposed OptoMonitor 3 is comparable to the predicate device, support substantial equivalence of the device that is the subject of this 510(k).

The results of the verification/validation tests and the risk analysis have demonstrated that the additional features incorporated in the OptoMonitor 3 device do not add any new questions of safety and efficacy and is therefore substantially equivalent to the predicate OptoMonitor System (K192340 cleared on 12/12/2019).