DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 13, 2016

Opsens, Inc.
% Chris Henza
Regulatory Consultant
Ultra Lifescience Solutions Inc
146 N. Greenview Ave
Mundelein, Illinois 60060

Re: K161263
Trade/Device Name: OptoMonitor II
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, DQX
Dated: August 9, 2016
Received: August 11, 2016

Dear Chris Henza:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161263

Device Name
OptoMonitor II

Indications for Use *(Describe)*

The OptoMonitor 2 is a system intended for use in all blood vessels, including coronary and peripheral vasculature, to measure intravascular pressure during angiography and/or interventional procedures.
Pressure measurements are obtained to provide hemodynamic information, such as FFR, for the diagnosis and treatment of blood vessel diseases. Pressure measurements are also obtained to provide intra-catheter or intravascular pressure, such as within occlusion perfusion catheter, for the diagnosis and treatment within the vasculature.

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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7 510(K) SUMMARY DOCUMENT K161263

7.1 SUBMITTER

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Date Prepared: May 2, 2016

7.2 DEVICE

Name of Device: OptoMonitor II

Common or Usual Name: Pressure Monitor

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

Regulatory Class: II

Product Code: DXO

7.3 PREDICATE DEVICE

OptoMonitor System cleared via K142598 (cleared on 06/12/2015). This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

7.4 DEVICE DESCRIPTION

The proposed OptoMonitor II is a new version of the OptoMonitor System that includes software modifications and new labeling to allow for the expanded indications of intravascular pressure monitoring during interventional procedures, such as with the occlusion perfusion catheter, for diagnosis and treatment within the vasculature. This device and its components are considered accessories to catheter pressure transducers and are intended for use with legally marketed catheters.

Software Description

The OptoMonitor II is intended to measure pressure using specifically devoted optical pressure sensing devices. The OptoMonitor II comprises two modes of operation:

1) FFR mode using an OptoWire (The FFR mode is exactly the same as the predicate device, there are no changes to FFR mode included in this submission.)

2) Pressure mode using an Optical Pressure Catheter (The Pressure mode is a new modality and the subject of this submission)

The OptoMonitor II automatically switches to the proper operational mode upon connecting the device.

This information is contained within the EEPROM contained in every device that connect to the OptoMonitor II.

Both modes are nearly the same with the following differences:

- The FFR mode includes the calculation and display of Pd/Pa and FFR values.
- The FFR mode includes the equalization of distal pressure against aortic pressure.
- The pressure mode includes atm (atmosphere) as pressure unit.
- The pressure mode does not allow re-zeroing the distal pressure of more than 50 mmHg when in mmHg, and of more than 300mmHg when in atm unit.
- The pressure is not output on the distal output interface when unit ATM (instead of mmHg).

Hardware Description

The proposed OptoMonitor-II includes the Optical Unit (OU), the Display Unit (DU), The Handle Unit (HU) and accessories (cables, power supply, etc). These hardware components are exactly the same as the cleared device hardware (K142598 cleared on 06/12/2015), software and labeling (to indicate updated software) is updated with this submission.

OptoMonitor-II is compatible with the cleared Occlusion Perfusion Catheter(OPC) devices as described in the FDA submissions K130525, K154554 & K153488. The OPC catheters are legally marketed devices that are not altered by Opsens. All sizes of Occlusion Perfusion Catheters are compatible with the OptoMonitor II device since the catheters are all within the specified pressure range and the connectors are compliant to Optomonitor requirements.

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

7.5 INDICATIONS FOR USE

The OptoMonitor 2 is a system intended for use in all blood vessels, including coronary and peripheral vasculature, to measure intravascular pressure during angiography and/or interventional procedures.

Pressure measurements are obtained to provide hemodynamic information, such as FFR, for the diagnosis and treatment of blood vessel diseases. Pressure measurements are also obtained to provide intra-catheter or intravascular pressure, such as within occlusion perfusion catheter, for the diagnosis and treatment within the vasculature.

7.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor II is a new version of the monitoring system that includes software modifications and new labeling where necessary to allow for the expanded indications of intravascular pressure monitoring during interventional procedures, such as with the occlusion perfusion catheter, for diagnosis and treatment within the vasculature.

The technological characteristics of the new modality raise a question concerning whether its performance can be expected to be equivalent with the additional catheter as with the predicate catheter. Performance testing has confirmed equivalence. No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

The identified questions of safety and efficacy apply to both the new device and the predicate and so the new device does not raise different questions of safety and efficacy. Therefore, the proposed device, OptoMonitor-II, meets substantial equivalence requirements with regards to the legally marketed predicate OptoMonitor System (K142598 cleared on 06/12/2015).

7.7 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.

The Risk Management Report for the OptoMonitor II was used to determine if there would be necessary updates for the additional modality "Pressure Mode" in relation to the safety measures applied in the existing design. Since the Pressure Mode is a software only update, hardware testing was not updated with this release. Validation testing confirms system functionality with the additional software modality.

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.

7.8 CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the proposed OptoMonitor II is comparable to the predicate device, support the safety and effectiveness of the device that is the subject of this 510(k), and ensure 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 the additional modality of "pressure Mode" does not add any new questions of safety and efficacy and is therefore substantially equivalent to the predicate OptoMonitor System (K142598 cleared on 06/12/2015).

7.9 SUBSTANTIAL EQUIVALENCE TABLE

Substantial Equivalence Table			
		Proposed Device	**Predicate Device (Primary)**
Regulatory Information	Name	OptoMonitor-II	OptoMonitor
	510(k)#	Pending	K142598
	Predicates	K142598	K111395 K041134
	Product Code	DXO	DQX, DXO
	Class	2	2
	Regulation Number	870.2870	870.1330, 870.2870
	Regulation Generic Name	Transducer, pressure, catheter tip	Wire, guide, catheter; Transducer, pressure, catheter tip
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.
	Indications	The OptoMonitor-II is a system intended for use in all blood vessels, including coronary and peripheral vasculature, to measure intravascular pressure during angiography and/or interventional procedures. Pressure measurements are obtained to provide hemodynamic information, such as FFR, for the diagnosis and treatment of blood vessel diseases. Pressure measurements are also obtained to provide intracatheter or intravascular pressure, such as within occlusion perfusion catheter, for the diagnosis and treatment within the vasculature.	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.
Technological Characteristics	Prescription Use	Rx Only	Rx Only
	System Components	Reusable signal processor / monitor Embedded software Connecting cables	Sterile, disposable guidewire Reusable signal processor / monitor Embedded software Connecting cables
	System Capabilities	Measurement of intravascular blood Pressure including FFR.	Measurement of intravascular blood pressure including FFR.
	Pressure Sensing & Signal Transmission Technology	Sensess pressure from Fiberoptic sensor.	Fiberoptic sensor & fiber bundle embedded in guidewire. Monitor Sensess pressure from Fiberoptic sensor.
	Operating Temperature (Monitor)	15°C to 30°C	15°C to 30°C

Substantial Equivalence Table			
		Proposed Device	**Predicate Device (Primary)**
	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 FFR and catheter low pressure range. Distal high pressure range between -1 (-760 mmHg) atm and 20 atm (152000 mmHg) in high pressure mode.	-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) The high pressure range shall have an accuracy of 4% of reading or 1% of the full scale range whichever is greater.	+/- 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	Touchscreen
	Auto-zeroing	Yes	Yes
	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
	Real Time Numerical Values	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa
	Recording Values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa
	Display Monitor	LCD	LCD
	Aortic Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)
	Distal pressure output	FFR mode remains unchanged.	Low level 5uV/mmHg

Substantial Equivalence Table			
		Proposed Device	**Predicate Device (Primary)**
	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 fOPC	OptoWire