DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2015

Opsens, Inc.
% Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K142598
Trade/Device Name: OptoWire and OptoMonitor System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: May 13, 2015
Received: May 14, 2015

Dear Pamela Papineau:

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.

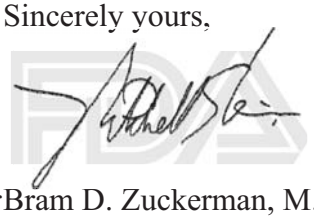
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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,



for 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)*
K142598

Device Name
OptoWire and OptoMonitor System

Indications for Use *(Describe)*
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.

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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Section 5 – 510(k) Summary

General Information

Owner's Name:	Opsens, Inc.
Address:	2014 rue Cyrille Duquet, #125 Quebec, QC G1N 4N6 Canada
Telephone:	418-682-9996
Fax Number:	418-682-9939
Contact Person:	Pamela Papineau, RAC (US, EU, CAN) Delphi Medical Device Consulting, Inc.
Address:	5 Whitcomb Avenue Ayer, MA 01432
Telephone Number:	(978) 772-3552
Fax Number:	(978) 796-5460

Subject Device:

Trade Name:	OptoWire and OptoMonitor System
Common Name:	Intravascular Pressure Monitoring System
Product Code:	DXQ / DXO
FDA Regulation:	21 CFR 870.1330 – Catheter Guide Wire 21 CFR 870.2870 – Catheter Tip Pressure Transducer
Device Classification:	Class II

Predicate Devices:

Product Name:	PrimeWire Prestige Plus Pressure Guide Wire (Volcano Corp.)
Common Name:	Pressure Guide Wire
Product Code:	DQX
FDA Regulation:	21 CFR 870.1330 – Catheter Guide Wire
Device Classification:	Class II
Premarket Notification:	K111395
Product Name:	ComboMap Pressure and Flow System (Volcano Corp.)
Common Name:	Intravascular Pressure Monitoring System
Product Code:	OBJ
FDA Regulation:	21 CFR 870.1200 – Diagnostic Intravascular Catheter
Device Classification:	Class II
Premarket Notification:	K041134

Indications 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.

Device Description:
The OptoWire and OptoMonitor System includes a pressure sensing guidewire (OptoWire), electronic signal processing and display units (OptoMonitor) that process signals received from the OptoWire to display intravascular blood pressure and fractional flow reserve (FFR) values, and various connection cables. The OptoWire and OptoWire cable are sterile, single-use devices; the remaining system components are reusable.

Substantial Equivalence:
The OptoWire and OptoMonitor System is substantially equivalent to the Volcano Corp. PrimeWire Prestige Plus Pressure Sensing Guidewire (K111395) and the Volcano Corp. ComboMap Pressure and Flow System (K041134). Substantial equivalence is based on indications for use, technological characteristics, device materials, performance characteristics; physical and functional test results, and conformity with standards. A substantial equivalence summary table is provided at the end of this 510(k) Summary.

Biocompatibility Testing:
Testing has been performed on the OptoWire device in accordance with the ISO 10993 family of standards to confirm that all patient-contacting materials are biocompatible. This testing included cytotoxicity, intracutaneous toxicity, acute systemic toxicity, sensitization, hemocompatibility and pyrogenicity.

Sterilization, Packaging and Shelf Llife:
The OptoWire is sterilized to a 10^{-6} SAL using an ethylene oxide process that has been validated in accordance with ISO 11135-1. The remaining system components are non-sterile. Testing has been performed to confirm that all packaging (sterile barrier and outer packaging) meets predetermined acceptance criteria with respect to sterile package seal strength and seal integrity, and that the packaging adequately protects all system components throughout transportation and storage. The sterile product shelf life has been validated through package and product testing of unaged devices as well as devices that have been held at an elevated temperature to simulate the labelled shelf life. Samples will also be tested after real time aging.

Software:
The OptoMonitor contains software that has been developed, documented and validated in accordance with industry standards (IEC 62304 – *Medical device software – Software life cycle processes*) and FDA guidance (*General Principles of Software Validation; Final Guidance for FDA and Industry*). Complete software design, risk and validation documents have been provided in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Software validation has demonstrated that the system software operates in accordance with design specifications and the system operates as intended when used for its intended use.

Electrical Safety and EMC Testing:
The OptoMonitor has been tested in accordance with IEC 60601-1 (*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*) to demonstrate electrical safety; testing in accordance with IEC 60601-1-2 (*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*) has confirmed electromagnetic compatibility.

Performance Testing – Bench:
Bench testing has been performed to confirm that the OptoWire and OptoMonitor System meets predetermined acceptance criteria and is substantially equivalent to the predicate devices. The following is a summary of the performance (bench) testing presented in this 510(k):

Component	Testing		Purpose	Met Acceptance Criteria?
OptoWire				
Mechanical / Functional Verification	• Tip Testing • Wire Flexibility/Support • Tensile Test • Torque Tests • Turn to Failure • Fatigue Test • Coating Testing • Compatibility Test • Surface Inspection • Corrosion Test • Dimensional testing	• Sensor Sensitivity to Bending • Pressure and Sensor Testing • Optical Contrast • Optical Sensor Testing • Ambient Pressure Range • Signal Loss • Connection/ Disconnection Testing • Age testing	• Functionality and Performance • Safety • Usability	**Yes**. All internal design criteria were successfully met. Subject device compared favorably to predicate devices tested.
OptoMonitor				
• SCU Hardware • DU Hardware • HCU Hardware • System	• visual & design • specs & environment • single fault conditions • electrical performance	• Age Testing • Transportation Testing • Cleaning	• Functionality and Performance • Reliability • Safety • Usability • Environmental	**Yes**. All internal design criteria were successfully met.

Performance Testing – Animal:
Animal studies have been performed to characterize the *in-vivo* performance of the OptoWire and OptoMonitor System, as compared to the predicate device and other currently marketed devices with the same indications for use. Animal testing included assessment of the system handling characteristics, compatibility with other devices, and pressure measurement capabilities.

Conclusion:
The OptoWire and OptoMonitor System has been demonstrated to be substantially equivalent to the predicate devices.

Substantial Equivalence Comparison

	OptoWire and OptoMonitor System (current submission; Opsens, Inc.)	PrimeWire Prestige Plus Pressure Guide Wire (K111395; Volcano Corp.)	ComboMap Pressure and Flow System (K041134; Volcano Corp.)
Device Common/Usual Name	Intravascular Pressure Guide Wire and Monitoring System	Intravascular Pressure Guide Wire	Intravascular Pressure Monitoring System
Device Class	Class II	Class II	Class II
Product Code / Regulation	DQX / 21 CFR 870.1330 DXO / 21 CFR 870.2870	DQX / 21 CFR 870.1330	OBJ / 21 CFR 870.2870
Regulation Name	Pressure Guide Wire Diagnostic Intravascular Monitor	Pressure Guide Wire	Diagnostic Intravascular Monitor
Indications for Use	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 disease.	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 for the diagnosis and treatment of blood vessel disease. Intended for use with signal processing system such as Volcano ComboMap.	A multi-mode system intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure and/or blood flow velocities during diagnostic angiography and/or interventional procedures. Intended for use with pressure sensing guidewire such as Volcano PrimeWire.
System Components	Sterile, disposable guidewire 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 and flow including FFR (when used with pressure/flow system)	Measurement of intravascular blood pressure and flow including FFR (when used with pressure wire)
Prescription Use	Rx Only	Rx Only	Rx Only
Pressure Sensing & Signal Transmission Technology	Fiberoptic sensor & fiber bundle embedded in guidewire	Hard wired strain gauge embedded in guidewire	Hard wired strain gauge embedded in compatible guidewire

	OptoWire and OptoMonitor System (current submission; Opsens, Inc.)	PrimeWire Prestige Plus Pressure Guide Wire (K111395; Volcano Corp.)	ComboMap Pressure and Flow System (K041134; Volcano Corp.)
Sterile, Single Use Patient Contact Component?	Yes – OptoWire	Yes – PrimeWire Prestige Plus	No – computer-controlled pressure and flow monitoring instrument intended for use with compatible pressure guidewire
FFR Capability?	Yes	Yes	Yes
FFR Viewing?	Yes	N/A	Yes
Basis for FFR Determination	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in OptoWire; aortic pressure from external pressure transducer	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in PrimeWire; aortic pressure from external pressure transducer	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in compatible guidewire; aortic pressure from external pressure transducer
Operating Temperature (Monitor)	15°C to 30°C	N/A	16°C to 32°C
Transport Temperature (Monitor)	-25°C to 60°C	N/A	-20°C to 60°C
Operating Relative Humidity (Monitor)	10% to 85% non-condensing	N/A	30% to 75%
Storage Temperature (Monitor)	Room Temperature	N/A	-20°C to 60°C
Operating Pressure	70 to 106 kPa	N/A	50 to 106 kPa
Pressure Range	-30 to 300 mmHg	-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)	Unknown	+/- 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	N/A
Zero Drift	<1 mmHg/h	Unknown	N/A
Electrical Isolation	Class 2 (double isolation)	N/A	Class 1
User Interface	Touchscreen	N/A	Touchscreen, Remote Control
Auto-zeroing	Yes	N/A	Yes

	OptoWire and OptoMonitor System (current submission; Opsens, Inc.)	PrimeWire Prestige Plus Pressure Guide Wire (K111395; Volcano Corp.)	ComboMap Pressure and Flow System (K041134; Volcano Corp.)
Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	N/A	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure, Pa/Pd trend curve
Real Time Numerical Values	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa	N/A	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa, heartbeat
Minimum Pd/Pa Cursor (Detection of FFR Locus)	Yes	N/A	Yes
Recording Values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	N/A	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa
Display Monitor	LCD	N/A	LCD
Aortic Input	High Level (100 mmHg/V)	N/A	High Level (100 mmHg/V) Low Level (5uV/V/mmHg)
Aortic Output	No	N/A	Low Level (5uV/V/mmHg)
Distal Input	OptoWire (optical)	N/A	Compatible pressure wire (PrimeWire) (electrical)
Distal Output	Low Level (5uV/V/mmHg)	N/A	Low Level (5uV/V/mmHg)
Guidewire OD	0.014”	0.014”	N/A
Guidewire Length	175 cm	185 cm, 300 cm	N/A
Guidewire Shaft Material	Stainless Steel; Nitinol	Stainless Steel; SS	N/A
Guidewire Coating	Teflon; Silicone	Teflon; GlyDx Hydrophilic coating	N/A
Guidewire Tip Configuration	Straight	Straight, pre-shaped “J”	N/A
Guidewire Tip Length	3.5 cm	3.0 cm	N/A
Radiopaque Tip?	Yes	Yes	N/A
Pressure Sensor Location	3.5 cm from distal tip	3.0 cm from distal tip	N/A