



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

February 11, 2016

Opsens
Vanessa Mootoosamy
Director Of Quality Assurance
2014, Cyrille Duquet Street, #125
Quebec, G1N 4N6 CA

Re: K152991

Trade/Device Name: OptoWire Deux pressure guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: January 7, 2016
Received: January 12, 2016

Dear Vanessa Mootoosamy:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152991

Device Name

OptoWire Deux pressure guidewire

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 005 510(k) Summary

General Information:	<p>Owner's Name: Opsens, Inc. Address: 2014 rue Cyrille Duquet, #125 Québec, QC G1N 4N6 Canada</p> <p>Contact Person: Vanessa Mootoosamy Opsens Inc. Director, Quality Assurance Address: 014 rue Cyrille Duquet, #125 Québec, QC G1N 4N6 Canada Telephone: 418-682-9996 ext. 239 Fax Number: 418-682-9939</p>
Subject Device:	<p>Trade Name: OptoWire Deux pressure guidewire Common Name: Catheter pressure guide wire Product Code: DQX / DXO FDA Regulation: 21 CFR 870.1330–Catheter Guide Wire 21 CFR 870.2870–Catheter Tip Pressure Transducer Device Classification: Class II</p>
Predicate Device:	<p>Trade Name: OptoWire and OptoMonitor System Common Name: Intravascular Pressure Monitoring System Product Code: DQX / DXO FDA Regulation: 21 CFR 870.1330 – Catheter Guide Wire 21 CFR 870.2870 – Catheter Tip Pressure Transducer Device Classification: Class II Premarket Notification: K142598</p>
Indications for Use:	<p>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.</p>
Description of device:	<p>The OptoWire Deux is a hybrid Nitinol/Stainless Steel pressure sensing guidewire that is a steerable guidewire with an optical pressure sensor mounted proximal to the 3.5 cm long radio opaque tip. The OptoWire Deux is for use in combination with Opsens' OptoMonitor system for blood pressure measurement. The OptoWire Deux has a diameter of 0.014" (0.36 mm) and an effective length of 175 cm. The OptoWire Deux is supplied preconnected to the OptoWire cable along with a torque device. The OptoWire cable is unique to each OptoWire and it must be used conjunctionally with the OptoWire supplied in the same tray. OptoWire Deux is supplied sterile, non-pyrogenic and is intended for single use only. The changes described in this special 510k device modification only affect the OptoWire. There are no change to the OptoMonitor device included in the cleared systems K142598.</p>

Labeling: There have been no change to the indications for use, warnings contraindications or precautions in comparison to the device cleared in K142598. The mode of operation remain the same. A minor change related to schematic in device labeling was performed to identify and describe the new device design feature.

Substantial Equivalence: The OptoWire Deux is substantially equivalent to the OptoWire One included in the OptoWire & OptoMonitor system (K142598).The OptoWire Deux pressure guide wire has the same technological characteristics and the same similarities to the predicate. A substantial equivalence summary table is provided at the end of this 510(k) Summary. The OptoWire Deux:

- have the same indication for use,
- use the same operating principle,
- incorporate the same basic design,
- are packaged and sterilized using the same materials and processes.

Statement on Fundamental technology: These changes do not in any way alter the device indications for use, or the fundamental scientific technology upon which the device is based.

Biocompatibility The OptoWire Deux new design has been tested in accordance with ISO 10993-1:2009 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process) to determine which tests are necessary to demonstrate biocompatibility of the patient-contacting materials present in the finished device. The OptoWire is characterized as an external communicating, direct-contact (circulating blood) device with limited (< 24 hours) patient contact. The following biocompatibility tests are recommended for such devices:

- | | |
|---------------------------|---------------------|
| • Cytotoxicity | • Systemic Toxicity |
| • Sensitization | • Hemocompatibility |
| • Intracutaneous Toxicity | • Pyrogenicity |

Each of these tests were performed on finished, sterilized OptoWire Deux samples; the results of this testing are summarized in this special 510(k). All testing was performed in accordance with Good Laboratory Practices. The sample devices met the acceptance criteria.

Performance Data The OptoWire Deux new design was subjected to the following test methods (bench test) to demonstrate that these devices comply with the performance data from the predicate device:

- | | |
|--------------------------|-------------------------|
| • Surface Inspection | • Turn-to-failure |
| • Catheter Compatibility | • Fatigue |
| • Torque Strength | • Torquability |
| • Flexibility (Support) | • Coating Pushability |
| • Tip Load | • Coating Durability |
| • Tip Flexibility | • Coating Damage |
| • Tensile Strength | • Particulates (USP788) |
| | • Pressure accuracy |

Sterilization, Packaging & Shelf Life

The OptoWire Deux, OptoWire Cable and Torque Device are sterile, single-use devices provided in a unit package consisting of a protective guidewire hoop, thermoformed tray and lid, which are sealed in a medical-grade Tyvek – polyester pouch. Each pouch is placed in a shelf box. The devices are sterilized in this configuration using a 100% ethylene oxide sterilization process that has been successfully validated in accordance with EN ISO 11135-1:2007 (Sterilization of healthcare products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices). The device sterility assurance level (SAL) is 10⁻⁶. The device will be labeled as non-pyrogenic. There have been no changes in the packaging or sterilization method. The OptoWire Deux was validated by way of a Product Adoption, where sterility was verified at fractional, bioburden and EO residual tests were also performed. The OptoWire Deux has a shelf life of 1 year and 3 years shelf life testing is currently on-going.

Conclusion (Statement of equivalence)

The results from these tests mentioned above:

- demonstrate that the technological and performance characteristics of the subject OptoWire Deux pressure guide wire 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 identical intended use.

The results of the verification/validation tests and the risk analysis have demonstrated that the OptoWire Deux Guidewire is in accordance with product specifications that were previously cleared for the predicate device (OptoWire and OptoMonitor System, cleared in 510(k) K142598).

Substantial Equivalence Table		
	OptoWire Deux	OptoWire One as part of OptoWire and OptoMonitor System (Predicate Device K142598; Opsens, Inc.)
Device Common Usual Name	Intravascular Pressure Guide Wire	Intravascular Pressure Guide Wire
Device Class	Class II	Class II
Product Code / Regulation	DQX / 21 CFR 870.1330 DXO / 21 CFR 870.2870	DQX / 21 CFR 870.1330 DXO / 21 CFR 870.2870
Regulation Name	Pressure Guide Wire Catheter tip pressure transducer	Pressure Guide Wire Catheter tip pressure transducer
Prescription Use	Rx Only	Rx Only
Indications for Use	The OptoWire Deux pressure guidewire is indicated 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	The OptoWire One pressure guidewire is indicated 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.

	diagnosis and treatment of blood vessel disease.	
Device Description	<p>The OptoWire Deux is a hybrid Nitinol/Stainless Steel pressure sensing guidewire that is a steerable guidewire with an optical pressure sensor mounted proximal to the 3.5 cm long radio opaque tip. The OptoWire Deux is for use in combination with Opsens' OptoMonitor system for blood pressure measurement. The OptoWire Deux has a diameter of 0.014" (0.36 mm) and an effective length of 175 cm. The OptoWire Deux is supplied pre-connected to the OptoWire cable along with a torque device. The OptoWire cable is unique to each OptoWire and it must be used conjunctionally with the OptoWire supplied in the same tray. OptoWire Deux is supplied sterile, non-pyrogenic and is intended for single use only</p> <p>The intermediate section comprises a hydrophilic coating.</p>	<p>The OptoWire One is a hybrid Nitinol/Stainless Steel pressure sensing guidewire that is a steerable guidewire with an optical pressure sensor mounted proximal to the 3.5 cm long radio opaque tip. The OptoWire One is for use in combination with Opsens' OptoMonitor system for blood pressure measurement. The OptoWire One has a diameter of 0.014" (0.36 mm) and an effective length of 175 cm. The OptoWire One is supplied pre-connected to the OptoWire cable along with a torque device. The OptoWire cable is unique to each OptoWire and it must be used conjunctionally with the OptoWire supplied in the same tray. OptoWire One is supplied sterile, non-pyrogenic and is intended for single use only.</p> <p>The intermediate section comprises a hydrophobic coating.</p>
System Components	Sterile, disposable guidewire	Sterile, disposable guidewire
System Capabilities	Measurement of intravascular blood pressure and flow including FFR (when used with OptoMonitor system)	Measurement of intravascular blood pressure and flow including FFR (when used with OptoMonitor system)
Pressure Sensing & Signal Transmission Technology	Fiber optic sensor & fiber bundle embedded in guidewire	Fiber optic sensor & fiber bundle embedded in guidewire
Sterile, Single Use Patient Contact Component?	Yes	Yes
Guidewire OD	0.014"	0.014"
Guidewire Length	175 cm	175 cm
Guidewire Shaft Material	Stainless Steel; Nitinol	Stainless Steel; Nitinol
Guidewire shaft section Coating	Teflon (PTFE)	Teflon (PTFE)
Guidewire intermediate section Coating	PET+ Hydrophilic coating	Silicone
Guidewire tip section Coating	Uncoated	Silicone
Guidewire Tip Configuration	Straight	Straight
Guidewire Tip Length	3.5 cm	3.5 cm
Radiopaque Tip?	Yes	Yes

Pressure Sensor Location	3.5 cm from distal tip	3.5 cm from distal tip
FFR Capability?	Yes	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 OptoWire; aortic pressure from external pressure transducer
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