



January 2, 2020

Opsens Inc.  
% Chris Henza  
Regulatory Consultant  
Ultra LifeScience Solutions Inc.  
872 S. Milwaukee Ave #286  
Libertyville, Illinois 60048

Re: K191907

Trade/Device Name: OptoWire III  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: DQX, DXO  
Dated: November 28, 2019  
Received: December 3, 2019

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. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning  
Assistant Director  
DHT2A: Division of Cardiac  
Electrophysiology, Diagnostics  
and Monitoring Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K191907

Device Name

OptoWire III

Indications for Use (Describe)

The OptoWire III 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.

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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## 5 510(k) SUMMARY OPTOWIRE III

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### 1. SUBMITTER

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Quebec (Quebec) G1P 4S3

**Phone:** 418.781.0333 ext 3408

**Fax Number:** 418-781-0024

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**Date Prepared:** July 12, 2019

### 2. DEVICE

**Name of Device:** OptoWire III

**Common or Usual Name:** Pressure Guidewire

**Classification name:** Wire, guide, catheter; Transducer, pressure, catheter tip

**Regulatory Class:** II

**Product Code:** DQX, DXO

### 3. PREDICATE DEVICE

OptoWire Deux cleared via K152991 (cleared on 02/11/2016). This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

### 4. DEVICE DESCRIPTION

The proposed OptoWire III is a new version of the OptoWire Deux that includes changes to strengthen the robustness of the product. Additional changes have been made to improve manufacturability. Changes include a reduction in tip length and coil gap, changes in the tube inner and outer configuration, and a minor material change in the PTFE coating.

The Opsens OptoWire III is used in conjunction with the Opsens OptoMonitor and Accessories, the "OptoMonitor System" consisting of an electronic signal processing and display units (OptoMonitor) that process signals received from the OptoWire to display intravascular blood pressure and hemodynamic information, such as fractional flow reserve (FFR) values, and various connection cables. The OptoMonitor is cleared in a separate 510(k), K142598.

The OptoWire III consists of the following items:

1. OptoWire assembly (guidewire) including the pressure sensor sub-assembly
2. Fiber Optic Interface Cable (FOIC)
3. Packaging including tray, Torque Device, pouch and box
4. Labelling including labels and printed IFU

## 5. 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.

## 6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoWire III is substantially equivalent to the *OptoWire Deux pressure guidewire* cleared in K152991 on Feb 11, 2016.

The proposed OptoWire III is a new version of the pressure guidewire that includes design changes from OptoWire Deux to OptoWire III (also referred to as OptoWire 3, OW 3, or OptoWire San (OW San)) is to strengthen the robustness of the wire. Additional changes were simultaneously implemented to optimize the manufacturing process. The proposed device and the predicate device are considered catheter guide wires and pressure transducer tips which are coded as DQX & DXO.

Indications for Use for the OptoWire III are exactly the same as the predicate device indications (K152991 on Feb 11, 2016).

The technological characteristics of the proposed OptoWire III include a reduction in tip length and coil gap, changes in the tube inner and outer configuration, and a minor material change in the PTFE coating. 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, OptoWire III, meets substantial equivalence requirements with regards to the legally marketed predicate OptoWire Deux (K152991 cleared on Feb 11, 2016).

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

		Proposed Device	Predicate Device
Regulatory Information	Name	OptoWire III	OptoWire Deux
	510(k)#	Pending	K152991
	Predicates	K152991	K142598
	Product Code	DOX, DXO	DOX, DXO
	Class	2	2
	Regulation Number	870.1330, 870.2870	870.1330, 870.2870
	Regulation Generic Name	Wire, guide, catheter; Transducer, pressure, catheter tip	Wire, guide, catheter; Transducer, pressure, catheter tip
Intended use	Regulation Intended Use	Coiled wire fits inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.  Catheter tip transmits mechanical or electrical property changes in relation to changes in blood pressure to accessory equipment for processing.	Coiled wire fits inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.  Catheter tip transmits mechanical or electrical property changes in relation to changes in blood pressure to accessory equipment for processing.
	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.

		Proposed Device	Predicate Device
Technological Characteristics	Prescription Use	Rx Only	Rx Only
	System Components	Sterile, disposable guidewire	Sterile, disposable guidewire
	System Capabilities	Measurement of intravascular blood pressure and flow including FFR. (when used with the OptoMonitor system)	Measurement of intravascular blood pressure and flow including FFR. (when used with the OptoMonitor system)
	Pressure Sensing & Signal Transmission Technology	Fiberoptic sensor & fiber bundle embedded in guidewire.	Fiberoptic sensor & fiber bundle embedded in guidewire.
	Sterile, Single Use Patient Contact Component?	Yes	Yes
	Guidewire OD	0.014"	0.014"
	Guidewire Length	180 cm	175 cm
	Guidewire Shaft Material	Stainless Steel, Nitinol	Nitinol
	Guidewire Shaft Design	Two tubes joined by a laser butt weld	Continuous outer tube supported by safety wires
	Guidewire Shaft Coating	Teflon (PTFE)	Teflon (PTFE)
	Guidewire Intermediate Section Coating	PET + Hydrophilic coating	PET + Hydrophilic coating

	Proposed Device	Predicate Device
Guidewire Tip section Coating	Uncoated	Uncoated
Guidewire Tip Configuration	Straight	Straight
Guidewire Tip Design	Coiled	Coiled
Guidewire Tip Length	3.0 cm	3.5 cm
Radiopaque Tip?	Yes	Yes
Pressure Sensor Location	3.0 cm from distal tip	3.5 cm from distal tip
Pressure Sensor Bonding	Stainless steel 304 ring, laser welded	Glass ring + adhesive
OptoWire Optical Connector	Adhesive	Connector capillary ring + adhesive
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	<1mmHg/h	<1mmHg/h

## 7. PERFORMANCE DATA

### Risk Based Approach

The Risk Management Report was prepared to document the evaluations and decisions made as well as necessary safety measures in the design and the manufacturing of the OptoWire III. Many of the risks are mitigated by design, labels, sterilization, packaging, and shelf life, and biocompatibility.

Since the OptoWire III is the third generation of the OptoWire device, the risk management process has leveraged the activities of previous generation OptoWire Deux device risk management process activities. The risk Management Report addresses the differences between the predicate/proposed device and specifically consider the impact of these changes including their intent as an improvement.

The risks related to all applicable hazards which were identified for the OptoWire III have been reduced to the acceptable level by mitigation. The OptoWire III 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.

#### **Sterilization, Packaging, Shelf life Testing:**

The following standards are utilized to show equivalence of Sterilization, Packaging, and Shelf life:

- ISO 11135-1 (2014) Sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)
- ISO 11607-1 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)
- ASTM F1980-07 (Reapproved 2011), standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)

#### **Biocompatibility testing:**

The biocompatibility evaluation was conducted in accordance with the FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (Attachment A) published June 16, 2016. This device is categorized in *ISO 10993-1:2018* as "External communicating device – circulating blood" per section 5.2.3 c). The device will have limited exposure, a cumulative sum of single, multiple or repeated duration of contact up to 24 h. Testing completed on this device includes:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Systemic toxicity (acute)
- Hemocompatibility
- Pyrogenicity (rabbit test)
- SC5b-9 complement
- Partial Tromboplastin Time

#### **Design Verification Pre-Conditioning:**

The OptoWire III devices were exposed to EtO and Simulated Distribution prior to the execution of testing as pre-conditioning. Additionally, testing with the indicator "T1" was completed on devices subjected to accelerated aging the equivalent of 1 year ("T0" = no aging).

#### **Design Verification:**

Testing was conducted based on requirements of the latest FDA guidance document on guidewires: FDA Draft Guidance *Coronary, Peripheral, and Neurovascular Guidewire*, dated June 15, 2018. All Design Requirements were verified for the OptoWire III.

Design Specification Verification and ISO 11070 Compliance were completed by documentation check and therefore did not use any OptoWire III product.

The Fiber Optic Interface Cable and Sensor are tested at a component level as some verification items are difficult or not possible to assess once the components are built into the OptoWire III.

The Design Check and Functional testing are performed on finished devices with pre-conditioning. Since the design check consists of physical measurements and inspections, the test is only completed on unaged products. The Functional testing is completed on both unaged (T0) and aged (T1) products.

Mechanical Performance testing are performed on finished devices with pre-conditioning as specified in the protocols. Certain tests that relate to improvements from the OptoWire Deux also include a comparison to the predicate device (without any pre-conditioning). These tests include: Mechanical tests for Tip Flexibility, Tensile Strength, Torquability, Catheter Compatibility, Kink Resistance test, Bending test, Coating Pushability and Durability. The Mechanical testing is completed on both unaged (T0) and aged (T1) products.

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

#### **Animal studies:**

Animal performance testing was completed to validate device functionality. The animal model was a porcine model (*Sus scrofa* – Hybrid farm pigs). A non-atherosclerotic swine model was chosen because the model has been used extensively for angiographic/pressure studies, resulting in a large volume of data on its vascular response and correlation to humans. The study included 1 female pig and one spare animal that was not used.

The performance of the Optowire III was compared to the Optowire Deux in the LCx, LAD and LAD side branches. The evaluation consisted of tests to confirm compatibility with coronary arteries by examining the following criteria:

1. Guidewire atraumaticity
  - Tip flexibility
  - Guidewire flexibility
2. Trackability
  - Steerability
  - Torquability

#### Pushability

3. Catheter compatibility
  - Restriction
  - Support (deliverability)
4. Stent compatibility
5. Radiopacity and pressure waveform

Results were recorded as less than average, average, greater than average, and “workhorse”. The OptoWire III obtained a ‘workhorse’ score for most of the parameters evaluated and demonstrated a similar performance as the control, OptoWire Deux, for the pressure waveform and radiopacity. It can be concluded based on the results that the OptoWire III is substantially equivalent to the control.

## 8. CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the proposed OptoWire III 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 OptoWire III does not raise any new questions of safety and efficacy and is therefore substantially equivalent to the predicate OptoWire Deux (K152991 on Feb 11, 2016).