September 14, 2022

Opsens Inc.
% Christina Henza
Consultant
Ultra Lifescience Solutions, Inc.
2811 Milton Ave, #409
Janesville, Wisconsin 53545

Re: K213854
Trade/Device Name: SavvyWire™ and OptoMonitor 3
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO, LDF
Dated: August 9, 2022
Received: August 9, 2022

Dear Christina 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213854

Device Name
SavvyWire™

Indications for Use *(Describe)*

The SavvyWire™ is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures, while measuring the pressure within the heart allowing calculation of hemodynamic parameters.

Additionally, the SavvyWire™ can be used for temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213854

Device Name
OptoMonitor 3

Indications for Use *(Describe)*

The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during structural heart procedures.

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)

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510(K) SUMMARY SAVVYWIRE™

1. SUBMITTER

Address: Opsens, Inc.

750, Boulevard du Parc Technologique

Quebec (Quebec) G1P 4S3

Phone: 418.781.0333 ext 3408

Fax Number: 418-781-0024

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

Email: marc.chaunet@opsens.com

Date Prepared: September 13, 2022

2. DEVICE

Name of Device: SavvyWire™ and OptoMonitor 3

Common or Usual Name: structural wire with pacing and pressure sensing

Classification name: Wire, guide, catheter; Transducer, pressure, catheter tip, electrode, pacemaker, temporary

Regulatory Class: II

Product Code: DQX, DXO, LDF

3. PREDICATE DEVICE

The proposed SavvyWire™ is substantially equivalent to the Opsens existing pressure guidewire, OptoWire III cleared in K191907 on 01/02/2020 [Primary Predicate], and the Wattson Temporary Pacing Guidewire cleared in K192454 on 01/15/2020 [Secondary predicate], with the Lake Region Medical Pre-Formed Guidewire (Boston Scientific Safari^2 Pre-Shaped TAVI Guidewire) cleared in K151244 on 06/11/2015 used as a primary reference device.

The primary and secondary predicates (Predicate #1, Predicate #2) are included to support the pressure sensing and pacing indications / technologies as indicated below in accordance with the multiple predicates example 4 for a multi-parameter device from FDA guidance *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued on: July 28, 2014.

The Lake Region Medical Pre-Formed Guidewire (Boston Scientific Safari^2 Pre-Shaped TAVI Guidewire) cleared in K151244 on 06/11/2015 is used as a reference device (Reference #1) for the mechanical testing performed on the SavvyWire to demonstrate substantial equivalence. The Pacel™ Bipolar Pacing

Catheters cleared in K152784 on 10/22/2015 is used as a secondary reference (Reference #2) device to support the pacing function. Bundled together with this new device is a minor change to the OptoMonitor 3 software included in K202943 cleared on 11/24/2020 (Predicate #3) which expands the software to include a separate TAVI interface for use with the new wire. The predicate and reference devices have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The proposed SavvyWire™ is a new Catheter guidewire that includes functions for a structural wire, a pressure wire, and a pacing wire (temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.). Throughout the submission this will be referred to as either SavvyWire™ or Opsens Structural Wire (OSW). These two names are interchangeable and represent branding name vs. internal descriptive name.
SavvyWire™ is intended to be used with the OptoMonitor 3 (K202943), and ideally with the OpM3-DU TAVI, which is based on the approved OptoMonitor 3 (K202943), with a fully integrated TAVI software update.

5. INDICATIONS FOR USE

SavvyWire™: The SavvyWire™ is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures, while measuring the pressure within the heart allowing calculation of hemodynamic parameters.

Additionally, the SavvyWire™ can be used for temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.

OptoMonitor 3: The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during transcatheter aortic valve procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed SavvyWire™ is substantially equivalent to the Lake Region Medical Pre-Formed Guidewire (Boston Scientific Safari^2 Pre-Shaped TAVI Guidewire) cleared in K151244 on on 06/11/2015 [primary predicate], Opsens existing pressure guidewire, OptoWire III cleared in K191907 on 01/02/2020 [Secondary Predicate], and the Wattson Temporary Pacing Guidewire cleared in K192454 on 01/15/2020 [Tertiary predicate]. The Pacel™ Bipolar Pacing Catheters cleared in K152784 on 10/22/2015 is used as a reference device to support the pacing function. The secondary and tertiary predicates are included to support the pressure sensing and pacing indications / technologies as indicated below in accordance with the multiple predicates example 4 for a multi-parameter device from FDA guidance *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued on: July 28, 2014. Bundled together with this new device is a minor change to the OptoMonitor 3 software included in K202943 cleared on 11/24/2020 (Predicate 4) which expands the software to include a separate TAVI

interface for use with the SavvyWire™. It is appropriate to bundle the two devices because they are intended to be used together as a system during a therapeutic or diagnostic procedure.

The proposed SavvyWire™ indications for use are a blend of the three predicate devices since the proposed device includes functionalities supported by each of these. The OptoMonitor 3 indications were updated slightly to encompass the new modality including addition of pressure measurements in heart chambers and addition of measurements such as aortic valve gradients during transcatheter aortic valve replacement procedures.

The technological characteristics of the proposed SavvyWire™ encompass the functionalities of the predicate and reference devices including functions for a structural wire, a pressure wire, and a pacing wire (temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart). Each of these functions is fully supported by the relevant predicate/reference devices. Beyond the major difference of combining these functionalities, there is a slight difference in the pacing wire. The SavvyWire™ is unipolar where the reference device and predicate device 3 are bipolar. This necessitates the use of a separate patient electrode for the positive connection to the external pulse generator. The pacing of the SavvyWire™ is tested to be equivalent to that of the reference device, Pacel™ Bipolar Pacing Catheters in an animal study comparing the two devices and clinical performance is also confirmed via a clinical study. No new questions of safety and effectiveness were identified during the execution of Verification and Validation activities.

Therefore, the proposed devices, SavvyWire™ and OptoMonitor 3 with TAVI meet substantial equivalence requirements with regards to the legally marketed predicates (Predicate 1) the Lake Region Medical Pre-Formed Guidewire (Boston Scientific Safari^2 Pre-Shaped TAVI Guidewire) cleared in K151244, (Predicate 2) OptoWire III cleared in K191907, (Predicate 3) Watson Temporary Pacing Guidewire cleared in K192454 on 01/15/2020, (Predicate 4) predicate OptoMonitor 3 cleared in K202943 and the reference device, Pacel™ Bipolar Pacing Catheters cleared in K152784.

For detailed comparison, refer to the Substantial Equivalence tables on the following pages. Note that the comparison of the SavvyWire™ is included in Table 1: SavvyWire™ while the comparison for the OptoMonitor 3 is included in Table 2:OptoMonitor 3 with TAVI.

TABLE 1: SAVVYWIRE™

SavvyWire™						
		Proposed Device	**Predicate 1 (Primary Predicate)**	**Predicate 2**	**Reference Device**	**Predicate 3**
Regulatory Information	Name	SavvyWire™	Pre-Formed Guidewire (BSC Safari2)	OptoWire III	Pacel Bipolar Pacing Catheters	Wattson Temporary Pacing Guidewire
	510(k)#	K213854	K151244	K191907	K152784	K192454
	Predicates	K151244, K191907	K130798	K152991	K875059	K181001, K800298
	Product Code	DQX, DXO, LDF	DQX	DQX, DXO	LDF	DQX, LDF
	Class	2	2	2	2	2

SavvyWire™						
		Proposed Device	**Predicate 1 (Primary Predicate)**	**Predicate 2**	**Reference Device**	**Predicate 3**
	Regulation Number	870.1330, 870.2870, 870.3680	870.2870	870.1330, 870.2870	870.3680	870.1330, 870.3680
	Regulation Generic Name	Wire, guide, catheter; Transducer, pressure, catheter tip, electrode, pacemaker, temporary	Wire, guide, catheter;	Wire, guide, catheter; Transducer, pressure, catheter tip	Electrode, pacemaker, temporary	Wire, guide, catheter; Electrode, pacemaker, temporary
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. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.	Coiled wire fits inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.	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.	The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.	Coiled wire fits inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

SavvyWire™						
		Proposed Device	**Predicate 1 (Primary Predicate)**	**Predicate 2**	**Reference Device**	**Predicate 3**
	Indications	The SavvyWire™ is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures, while measuring the pressure within the heart allowing calculation of hemodynamic parameters. Additionally, the SavvyWire™ can be used for temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.	The Pre-Formed guidewires are intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those used within transcatheter aortic valve procedures.	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.	The St. Jude Medical Pacel™ Bipolar Pacing Catheters are intended for use in the intracardiac pacing and/or ECG recording	The Wattson temporary pacing guidewire is intended to introduce and position catheters and other interventional devices within the chambers of the heart , including those used within transcatheter aortic valve replacement (TAVR) procedures and balloon aortic valvuloplasty (BAV), while transmitting an electrical signal from an external pulse generator to the heart. The temporary pacing guidewire is not intended to remain in place following the clinical procedure.

SavvyWire™						
		Proposed Device	**Predicate 1 (Primary Predicate)**	**Predicate 2**	**Reference Device**	**Predicate 3**
	Contraindications	Cerebral vasculature & absence of anti-coagulation therapy	Cerebral vasculature	Cerebral vasculature	Patients with recurrent sepsis or with a hypercoagulable state should not be considered candidates for transvenous catheters since the catheter could serve as a focal point for septic or bland thrombus formation. In addition, patients with a mechanical tricuspid valve should not be considered for ventricular pacing.	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovascular.
Technological Characteristics	Prescription Use	Rx Only	Rx Only	Rx Only	Rx Only	Rx Only
	System Components	Sterile, disposable guidewire	Sterile, disposable guidewire	Sterile, disposable guidewire	Sterile, disposable catheter	Sterile, disposable catheter
	Pressure Sensing & Signal Transmission Technology	Fiberoptic sensor & fiber bundle embedded in guidewire.	None.	Fiberoptic sensor & fiber bundle embedded in guidewire.	None	None
	Sterile, Single Use Patient Contact Component?	Yes	Yes	Yes	Yes	Yes
	Guidewire OD	0.035"	0.035"	0.014”	Multiple catheter sizes available.	0.035”
	Guidewire Length	280 cm	275 cm	180 cm	110 cm	280 cm
	Guidewire Shaft Material	Stainless steel	Stainless steel	Stainless Steel, Nitinol	Stainless steel	Stainless Steel
	Tip Coating	None (Stainless steel)	Teflon spray coating (PFTE)	None (Platinum-Tungsten alloy)	None (Stainless steel)	None (Stainless steel)
	Shaft Coating	Teflon (PTFE)	Teflon (PTFE)	Teflon (PTFE)	Proprietary blend of polyurethane coating (hemocompatible)	Fluropolymer outer Jacket (FEP) with Silicone Oil Lubricant
	Intermediate Section Coating	Teflon (PTFE)	Teflon (PTFE)	PET + Hydrophilic coating		
	Tip Configuration	Spiral (XS OD 3.2 cm, S OD 4.2 cm)	Spiral (XS OD 3.2 cm, S OD 4.2 cm)	Straight	Various L and J curves available	Spiral (OD is 3.0 cm)
	Guidewire Tip Design	Coiled	Coiled	Coiled	Solid Core	Coiled
	Guidewire Tip Length	XS: 2.9 cm S: 3.8 cm	XS: 2.9 cm S: 4.2 cm	3.0 cm	Various lengths	Not specified

SavvyWire™						
		Proposed Device	**Predicate 1 (Primary Predicate)**	**Predicate 2**	**Reference Device**	**Predicate 3**
	Radiopaque Tip?	Yes	Yes	Yes	Yes	Yes
	Pressure Sensor Location	XS: 2.9 cm S: 3.8 cm	N/A	3.0 cm from distal tip	N/A	N/A
	Electrode	Unipolar	N/A	N/A	Bipolar	Bipolar
	External Pulse Generator Connection	Alligator clamp (negative lead) is connected to one of the SavvyWire pacing connection zones	N/A	N/A	Pins are connected to negative and positive terminals.	Removable guidewire adapter terminating in two shrouded positive/negative connectors
	Pulse Generator compatibility	Compatible with standard external pulse generators	N/A	N/A	Compatible with standard external pulse generators	Compatible with standard external pulse generators

TABLE 2:OPTOMONITOR 3 WITH TAVI

OptoMonitor 3 with TAVI			
		OptoMonitor 3 (with TAVI)	**OptoMonitor 3 (Predicate Device 4)**
Regulatory Information	Device Name	OptoMonitor 3	OptoMonitor 3
	510(k)#	K213854	K202943
	Product Code	DXO	DXO
	Class	2	2
	Regulation Number	870.2870	870.2870
	Regulation Generic Name	transducer, pressure, catheter tip	transducer, pressure, catheter tip
Intended use	Indications for Use	The OptoMonitor 3 is intended to measure cardiovascular blood pressure, including in heart chambers, coronary vessels and peripheral vessels, during interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve for the diagnosis and treatment of blood vessels and such as valve gradients during transcatheter aortic valve procedures.	The OptoMonitor 3 is intended 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.
	Prescription Use	Rx Only	Rx Only
Technological Characteristics	System Components / device materials	Reusable signal processor / monitor Embedded software Connecting cables	Reusable signal processor / monitor Embedded software Connecting cables
	System Capabilities	Measurement of intravascular blood pressure including FFR and measurement inside left ventricle	Measurement of intravascular blood pressure including FFR.

OptoMonitor 3 with TAVI			
		OptoMonitor 3 (with TAVI)	**OptoMonitor 3 (Predicate Device 4)**
	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.
	Operating Temperature (Monitor)	15°C to 30°C	15°C to 30°C
	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	-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
	Electrical Isolation	Class 2 (double isolation)	Class 2 (double isolation)
	User Interface	Touchscreen Control room: yes	Touchscreen Control room: yes
	Auto-zeroing	Yes	Yes
	Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, pressure wire 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 pressure wire pressure, mean Pd/mean Pa; FFR, dPR. Averaged pulse rate, systolic/diastolic values, gradients, left ventricular end of diastole pressure	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa; FFR, dPR
	Recording Values	Instantaneous Pa, pressure wire and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR. pulse rate, systolic/diastolic values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa; FFR, dPR
	Display Monitor	LCD	LCD

OptoMonitor 3 with TAVI			
		OptoMonitor 3 (with TAVI)	**OptoMonitor 3 (Predicate Device 4)**
	Aortic Input	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)
	Pressure wire Input	OptoWire™ (optical) and SavvyWire™ (optical)	OptoWire (optical)
	AUX Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)
	Distal pressure output	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)
	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™ SavvyWire™	OptoWire™

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 SavvyWire™. A full set of new risk management documents in accordance with ISO 14971 have been created for the SavvyWire™ including a Risk Management Plan, Hazard and risk analysis, FMEAs, and a Risk Management Report. Risk Management documentation as well as all testing associated with the OptoMonitor 3 with TAVI are included in the software risk management file as the OptoMonitor 3 device is a currently marketed device and the only changes are software related (addition of TAVI).

The risks related to all applicable hazards which were identified for the SavvyWire™ have been reduced to the acceptable level by mitigation. The SavvyWire™ 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
- SC5b-9 complement

Design Verification Pre-Conditioning:

The SavvyWire™ devices were exposed to EtO and Simulated Distribution prior to the execution of testing as pre-conditioning. Additionally, testing with the indicator "T2" was completed on devices subjected to accelerated aging the equivalent of 2 years ("T0" = no aging).

Electrical Safety:

The OptoMonitor 3 with TAVI Software complies with applicable requirements of IEC 60601-1 safety standard, IEC 60601-1-2 EMC standard, and IEC 60601-2-34 safety and performance standard when used in combination with the SavvyWire™. Certain applicable portions of ISO 14708 are also applied.

Design Verification:

Testing was conducted based on requirements of the latest FDA guidance document on guidewires: FDA Guidance *Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling Guidance for Industry and Food and Drug Administration Staff October 2019*. All Design Requirements were verified for the SavvyWire™ device.

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

Verification testing includes:

- Rapid Pacing Testing
- Mechanical Testing
- Functional Testing
- FOIC Testing

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 and to provide comparison data to the predicate devices. The use of the device is compared to the TAVI Guidewire: Safari^2, Boston Scientific (Lake Region Medical Pre-Formed Guidewire K151244) (predicate device) and the Rapid Pacing Wire: Pacel™ Bipolar Pacing Catheter, St-Jude Medical (K161873). Necropsy and Histopathology was also performed.

All acceptance criteria were met regarding risks and device functionality.

Clinical Studies

A single-arm, two-center, prospective study. The SavvyWire™ guidewire was used in eligible subject for rapid pacing runs, valve delivery and for pressure measurements pre- and post-THV deployment. The study included 20 patients; male and female subjects were eligible for this study if they were ≥18 years of age and were undergoing a TAVR procedure due to severe symptomatic aortic stenosis. Twenty one (21) devices were used; one per patient except the first patient needed two.

All substantial equivalence requirements were met. The experience reported here shows that the use of the SavvyWire™ guidewire in the LV for rapid ventricular pacing and appropriate advancement and positioning of the THV system during TAVR with both balloon expandable and self-expandable valves is substantially equivalent to other marketed devices as indicated in the identified predicates of section 3.

8. CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the SavvyWire™ is comparable to the predicate and reference devices, supports the substantial equivalence of the device that is the subject of this 510(k), and ensures 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 SavvyWire™ and OptoMonitor 3 with TAVI does not raise any new questions of safety and efficacy and is therefore substantially equivalent to the legally marketed predicate devices (Predicate 1) the Lake Region Medical Pre-Formed Guidewire (Boston Scientific Safari^2 Pre-Shaped TAVI Guidewire) cleared in K151244, (Predicate 2) OptoWire III cleared in K191907, (Predicate 3) Watson Temporary Pacing Guidewire cleared in K192454 on 01/15/2020, (Predicate 4) predicate OptoMonitor 3 cleared in K202943 and the reference device, Pacel™ Bipolar Pacing Catheters cleared in K152784