May 24, 2024

Opsens Inc.
Marc Chaunet
Regulatory Affairs Director
750, Boulevard du Parc Technologique
Quebec, QC G1P 4S3
Canada

Re: K240864
Trade/Device Name: PacePro Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, LDF
Dated: March 27, 2024
Received: March 28, 2024

Dear Marc Chaunet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2024.05.24 12:10:01 -04'00'

Sara Royce
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

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)*
K240864

Device Name
PacePro Wire

Indications for Use *(Describe)*
The PacePro Wire is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures.

Additionally, the PacePro Wire 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.

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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510(K) SUMMARY FOR PACEPRO WIRE

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 Director

Email: marc.chaunet@opsens.com

Date Prepared: March 27, 2024

2. DEVICE

Name of Device: PacePro Wire

Common or Usual Name: Structural guidewire with temporary pacing capabilities

Classification name: Wire, guide, catheter; electrode, pacemaker, temporary

Regulatory Class: II **Product**

Code: DQX, LDF

3. PREDICATE DEVICE

The proposed PacePro Wire™ is substantially equivalent to the Opsens existing guidewire, SavvyWire™ cleared in K213854 on 09/14/2022.

The subject device is physically the same product as the SavvyWire, without the pressure sensing capabilities. The predicate device has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The proposed PacePro Wire is a guidewire that includes functions for a structural 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 PacePro Wire or Opsens Pacing Wire (OPW). These two names are interchangeable and represent branding name vs. internal descriptive name.

5. INDICATIONS FOR USE

The PacePro Wire is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures.

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed PacePro Wire is substantially equivalent to the SavvyWire™ cleared in K213854 on 09/14/2022.

The proposed PacePro Wire indications for use are essentially the same as for the SavvyWire, minus the following portion "while measuring the pressure within the heart allowing calculation of hemodynamic parameters" as the subject device does not feature the pressure measurement capabilities of the cleared predicate SavvyWire.

The technological characteristics of the proposed PacePro Wire encompass the functionalities of the predicate device including functions for a structural 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 device. Identical to the SavvyWire, the PacePro Wire is unipolar. This necessitates the use of a separate patient electrode for the positive connection to the external pulse generator. The pacing capabilities of the PacePro Wire is tested to be equivalent to that of the predicate device. No new questions of safety and effectiveness were identified during the execution of Verification and Validation activities.

Therefore, the proposed devices, PacePro Wire meets substantial equivalence requirements with regards to the legally marketed predicate SavvyWire cleared in K213854.

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

TABLE 1: PACEPRO WIRE COMPARISON TABLE

		Proposed Device	**Predicate Device**	**Differences**
Regulatory Information	Name	Pace Pro Wire	SavvyWire™	N/A
	510(k)#	Pending	K213854	N/A
	Predicates	K213854	K151244, K191907	N/A
	Product Code	DQX, LDF	DQX, DXO, LDF	Same except for DXO
	Class	2	2	Same
	Regulation Number	870.1330, 870.3680	870.1330, 870.2870, 870.3680	Same except for 870.2870
	Regulation Generic Name	Wire, guide, catheter; electrode, pacemaker, temporary	Wire, guide, catheter; Transducer, pressure, catheter tip, electrode, pacemaker, temporary	Same except for "Transducer,

				pressure, catheter tip"

		Proposed Device	Predicate Device	Differences
Intended use	Regulation Intended Use	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.	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.	Same except for "Catheter tip transmits mechanical or electrical property changes in relation to changes in blood pressure to accessory equipment for processing."
	Indications	The PacePro Wire™ is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures. Additionally, the PacePro Wire™ can be used for temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.	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.	Same except for "while measuring the pressure within the heart allowing calculation of hemodynamic parameters" not relevant for the subject device PacePro Wire.
	Contraindications	Cerebral vasculature & absence of anti-coagulation therapy	Cerebral vasculature & absence of anticoagulation therapy	Same
Technological Characteristics	Prescription Use	Rx Only	Rx Only	Same
	System Components	Sterile, disposable guidewire	Sterile, disposable guidewire	Same
	Pressure Sensing & Signal Transmission Technology	N/A	Fiberoptic sensor & fiber bundle embedded in guidewire.	There are no fiberoptic sensor & fiber bundle embedded in the PacePro Wire guidewire
	Sterile, Single Use Patient Contact Component?	Yes	Yes	Same

	Guidewire OD	0.035"	0.035"	Same
	Guidewire Length	280 cm	280 cm	Same
	Guidewire Shaft Material	Stainless steel	Stainless steel	Same
	Tip Coating	None (Stainless steel)	None (Stainless steel)	Same
	Shaft Coating	Teflon (PTFE)	Teflon (PTFE)	Same
	Intermediate Section Coating	Teflon (PTFE)	Teflon (PTFE)	
	Tip Configuration	Spiral (XS OD 3.2 cm, S OD 4.2 cm)	Spiral (XS OD 3.2 cm, S OD 4.2 cm)	Same

		Proposed Device	**Predicate Device**	**Differences**
	Guidewire Tip Design	Coiled	Coiled	Same
	Guidewire Tip Length	XS: 2.9 cm S: 3.8 cm	XS: 2.9 cm S: 3.8 cm	Same
	Radiopaque Tip?	Yes	Yes	Same
	Pressure Sensor Location	XS: 2.9 cm S: 3.8 cm	XS: 2.9 cm S: 3.8 cm	Same
	Electrode	Unipolar	Unipolar	Same
	External Pulse Generator Connection	Alligator clamp (negative lead) is connected to one of the PacePro Wire pacing connection zones	Alligator clamp (negative lead) is connected to one of the SavvyWire pacing connection zones	Same
	Pulse Generator compatibility	Compatible with standard external pulse generators	Compatible with standard external pulse generators	Same

7. PERFORMANCE DATA

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 (2019) – Amendment 1:2023 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems

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:

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 successfully verified for the PacePro Wire device.

Design verification testing included:

- Mechanical Testing
- Particulate Testing
- Rapid Pacing Testing

No new questions of safety and effectiveness were identified during execution of Verification and Validation activities.

Animal studies:

No animal studies were necessary in support of the substantial equivalence of the PacePro Wire as the intended use/indications for use and technological characteristics are equivalent to the predicate device.

Clinical Studies

No clinical studies were necessary in support of the substantial equivalence of the PacePro Wire as the intended use/indications for use and technological characteristics are equivalent to the predicate device.

8. CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the PacePro Wire is comparable to the predicate device, 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 for the shared intended use.

The results of the verification/validation tests have demonstrated that the PacePro Wire does not raise any new questions of safety and efficacy and is therefore substantially equivalent to the legally marketed predicate device, the SavvyWire cleared in K213854.