January 9, 2026

Solo Pace Inc
% Nancy Frame
Regulatory Consultant
Gateway Medical Consulting Services, LLC
5 Scotch Pine Ln
St Paul, Minnesota 55127

Re: K252674
Trade/Device Name: Solo Pace Fusion System (SOLOFUSE1)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX, LDF
Dated: December 8, 2025
Received: December 10, 2025

Dear Nancy Frame:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

HETAL B. ODOBASIC -S

Hetal Odobasic
Director
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)*
K252674

Device Name
Solo Pace Fusion System (SOLOFUSE1)

Indications for Use *(Describe)*
Solo Pace Fusion is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures. Solo Pace Fusion can be used for temporary intracardiac pacing by transmitting an electrical signal from Solo Pace Control 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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: December 7, 2025

510(k) Number: K252674

Submitter's Name / Contact Person

Manufacturer
Solo Pace Inc
1201 Sutter Street
Suite 303
San Francisco, CA 94109 USA Establishment Registration # 3035372913

Contact Person
Nancy Frame
Regulatory Consultant
Tel: 763.300.3167 (direct)
nframe@gatewayMCS.com

General Information

Trade Name	Solo Pace Fusion System
Common / Usual Name	Catheter Guidewire
Classification Name	21 CFR 870.1330, Catheter Guidewire, DQX, Class II Secondary Product Code: LDF
Predicate Device	K213854, SavvyWire (Opsens Inc)
Reference Device	K230637 Wattson temporary pacing guidewire
Reference Device	K181001 Confida Brecker Guidewire

Device Description

The Solo Pace Fusion System consists of the following components:

- Fusion Guidewire
- Fusion Ground Pad
- Fusion Connection Cable
- Solo Pace Control System, consisting of the following:
    - Solo Pace Remote Control Module (RCM), packaged with the Fusion Guidewire, Fusion Ground Pad and Fusion Connection Cable
    - Solo Pace External Pulse Generator (EPG) (sold separately)

The Fusion Guidewire is intended to deliver interventional devices into the heart and serve as the pacing conduit when used with the Solo Pace Control system. The Fusion Guidewire is made of stainless steel and includes a pre-shaped pigtail distal tip. The Fusion Guidewire has a diameter of 0.035" (0.89 mm) and a length of 275 cm. The Fusion Guidewire is supplied with a tip insertion tube to help advance the guidewire into a catheter. A PTFE coating covers the shaft for lubricity. The proximal 8mm is uncoated to allow connection of the Fusion Guidewire to the Fusion Connection Cable. The pigtail is coated with silicone for lubricity. The Fusion Guidewire is supplied sterile, non-pyrogenic and is intended for single use only.
The Fusion Ground Pad is a transcutaneous pad placed on the patient to serve as the anode terminal for unipolar pacing via a unique connection to the Fusion Connection Cable. The Ground Pad acts as the return electrode for the pacing signal delivered to the patient's heart through the Fusion Guidewire. The Ground Pad cable is 60 inches (1.5 m) long and the skin contacting surface area is 350 cm^2.

The Fusion Connection Cable connects the Fusion Guidewire and the Fusion Ground Pad to the Solo Pace Control System (EPG component) in a manner that ensures proper polarity. The Fusion Connection Cable is approximately 60 inches (1.5 m) long.

The Solo Pace Control System RCM is a single use sterile device supplied with the Solo Pace Fusion System. The Solo Pace RCM connects wirelessly with the EPG to allow physician control of the EPG in the sterile field.

The Solo Pace Control System EPG is a reusable, external pulse generator described in detail in its Instructions for Use (IFU). The Solo Pace Control IFU should be reviewed, in its entirety, prior to the use of the Solo Pace Fusion System. Solo Pace Control was cleared for use under K241781.

Indications for Use

The Solo Pace Fusion System is intended to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve replacement procedures. Additionally, the Fusion System can be used for temporary intracardiac pacing by transmitting an electrical signal from Solo Pace Control to the heart.

Comparison of Technological Characteristics with the Predicate and Reference Device

A comparison of the technological characteristics between the Solo Pace Fusion System and the predicate and reference devices are provided in the following table.

Comparison of Technological Characteristics				
Characteristic	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Reference Device**
	Solo Pace Fusion System	**SavvyWire (K213854)**	**Wattson temporary pacing guidewire (K230637)**	**Confida Brecker Guidewire (K181001)**
Indications for Use	Solo Pace Fusion is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures. Solo Pace Fusion can be used for temporary intracardiac pacing by transmitting an electrical signal from Solo Pace Control 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.	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.	The Medtronic Confida™ Brecker Guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve implantation (TAVI).
Contraindication	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature	The guidewire contraindicated for patients presenting with an intolerance to anticoagulation therapy and unheparinized patients. The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.

Comparison of Technological Characteristics				
Characteristic	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Reference Device**
	Solo Pace Fusion System	**SavvyWire (K213854)**	**Wattson temporary pacing guidewire (K230637)**	**Confida Brecker Guidewire (K181001)**
Anatomical sites	Left Ventricle	Left Ventricle	Left Ventricle	Left Ventricle
Guidewire Shaft Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Length	275 cm	280 cm	280 cm	260 cm
Wire Compatibility	0.035”/0.89 mm	0.035”/0.89 mm	0.035”/0.89 mm	0.035”/0.89 mm
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Single Use of Reusable	Single Use	Single Use	Single Use	Single Use
Tip Coating	**Silicone**	**None (stainless steel)**	**Hydrophilic Coating**	**None (stainless steel)**
Shaft Coating	**PTFE**	**Teflon (PTFE)**	**Polyether ether ketone outer jacket (PEEK)**	**Polytetrafluoroethylene (PTFE)**
Intermediate Section Coating	**PTFE**	**Teflon (PTFE)**	**Polyether ether ketone outer jacket (PEEK)**	**Polytetrafluoroethylene (PTFE)**
Radiopacity	Yes	Yes	Yes	Yes
Tip Configuration	Pigtail (OD 3.2 cm)	Spiral (XS OD 3.2 cm, **S OD 4.2 cm**)	Pigtail	Preformed 360° curved tip.
Guidewire Tip Design	Coiled	Coiled	Coiled	Coiled
Guidewire Tip Length	3.0 cm	**XS 2.9 cm**	XS 3.0 cm	3.0 cm
Electrode	Unipolar	Unipolar	Bipolar	N/A
Grounding Method for Temporary Pacing	Fusion Ground Pad on the patient’s axilla	**Alligator clip connecting the pacemaker (positive) to a needle in incised skin at the arterial sheath site**	N/A	N/A
External Pulse Generator (EPG) Connections	Fusion Connection Cable	**Alligator clamp (negative) is connected to one of the SavvyWire pacing connection zones**	**Removable guidewire adapter terminating in two shrouded positive/negative connectors. Unshrouded adaptor pins are provided to ensure compatibility with all connecter cable terminals.**	N/A
Pulse Generator compatibility	Indicated for use with Solo Pace Control external pulse generators	Compatible with standard external pulse generators	Compatible with standard external pulse generators	N/A

Performance Data

Biocompatibility

The biocompatibility evaluation for the Solo Pace Fusion System was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Solo Pace Fusion Guidewire is considered an externally communicating device in contact with circulating blood and tissue for a limited period of time (<24 hours) during use. The Solo Pace Fusion Ground Pad is considered a surface skin device with intact skin for a limited period of time (<24 hours) during use. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

Performance Data - Bench

The device design was verified through performance, patient safety, structural integrity, infection, microbial and particulate contamination, and device interface tests.

Performance Data – Animal:

Good Laboratory Practice (GLP) Safety studies were performed to demonstrate the substantial equivalence of the Solo Pace Fusion System in comparison to the predicate SavvyWire and reference Wattson wire in a porcine model. The testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies. The subject Solo Pace Fusion System shares the same fundamental scientific technology as the predicate and reference device.

The GLP Safety studies demonstrated that the Solo Pace Fusion System performed similarly to the predicate and reference device with regard to adverse events and other animal health concerns. No animals experienced sustained arrhythmia in the post-rapid pacing monitoring period, all animals returned to normal sinus rhythm after rapid pacing was turned off, and there were no histological findings that indicate any differences between the subject device and its predicate and reference device.

Performance Data- Usability

A usability assessment for the Solo Pace Fusion System was conducted during the clinical trial entitled "Streamlined One-wire Logistics Optimizes Transcatheter Aortic Valve Replacement (SOLO-TAVR)".
The assessment included the first ten (10) SOLO-TAVR study cases using a variety of TAVR delivery systems. Usability scores averaged 4.97 out of 5.0. The 10 patient FIH usability study provides additional clinical evidence that Solo Pace Fusion usability with typical TAVR delivery systems and BAV systems is acceptable for human use.

Conclusion

Results of biocompatibility, benchtop, animal and usability studies performed on the Solo Pace Fusion System did not raise any new questions of safety or effectiveness compared to the predicate device. The Solo Pace Fusion System is substantially equivalent to the predicate device.