January 10, 2025

Solo Pace, Inc.
℅ Wanda Carpinella
Regulatory Consultant
Insight Medical Consulting, LLC
7 Barrows Road
Shrewsbury, Massachusetts 01545

Re: K241781
Trade/Device Name: Solo Pace Control
Regulation Number: 21 CFR 870.3600
Regulation Name: External pacemaker pulse generator
Regulatory Class: Class II
Product Code: DTE
Dated: December 12, 2024
Received: December 12, 2024

Dear Wanda Carpinella:

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,

Sara M. Royce -S

Digitally signed by Sara M. Royce -S
Date: 2025.01.10 13:26:19 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241781

Device Name
Solo Pace Control

Indications for Use *(Describe)*
The Solo Pace Control external pulse generator is used with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment by trained personnel. The external pulse generator can be used where short-term demand pacing is indicated for therapeutic purposes. The external pulse generator must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient. Specific indications for temporary pacing include, but are not limited to:

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Cardiac complications during invasive or surgical procedures
- Support, management, and evaluation of a patient before permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Interventional cardiology procedures where pacing is required

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

Traditional Premarket Notification 510(k) Summary

Solo Pace Control

510(k) Number K241781

Date Prepared: January 10, 2025

I. SUBMITTER

Solo Pace, Inc.
1201 Sutter St Suite 303
San Francisco, CA 94952

Contact Person

David Daniels, MD
Solo Pace, Inc.
1201 Sutter St Suite 303
San Francisco, CA 94109
415-385-9243

II. DEVICE

Name of Device: Solo Pace Control
Common or Usual Name: External pulse generator
Classification Regulation: 21 CFR §
Regulation Name: 870.3600 - External pacemaker pulse generator
Product Codes: DTE (Class 2) - Pulse-Generator, Pacemaker, External
Regulatory Class: II

III. PREDICATE

Name of Device: Medtronic Model 5392 External Pulse Generator (EPG)
Common or Usual Name: External pulse generator
Classification Regulation: 21 CFR §
Regulation Name: 870.3600 - External pacemaker pulse generator
Product Codes: DTE (Class 2) - Pulse-Generator, Pacemaker, External
Regulatory Class: II

IV. DEVICE DESCRIPTION

The Solo Pace EPG is an AC main powered with battery backup, single chamber, temporary pacemaker designed primarily for interventional cardiology procedures that require controlled pacing. It is a non-sterile component intended to be used outside the sterile field to provide temporary atrial or ventricular pacing as needed during a variety of interventional cardiac procedures. The Solo Pace EPG is bed mountable. It provides assistive operational workflow stages including: (1) pacing capture check; (2) rapid pacing; (3) control pacing; and (4) back-up pacing, which can be set by the physician based upon their preference. The Solo Pace EPG may also be operated in a manual mode, without any assistive modes. The Solo Pace EPG is configured to require the physician to make all clinical decisions (e.g., the presence or absence of contact with pace-able tissue, the presence or absence of 1:1 capture, appropriate conditions for rapid pacing.)

V. INDICATIONS FOR USE

The Solo Pace Control external pulse generator is used with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment by trained personnel. The external pulse generator can be used where short-term demand pacing is indicated for therapeutic purposes. The external pulse generator must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient. Specific indications for temporary pacing include, but are not limited to:

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Cardiac complications during invasive or surgical procedures
- Support, management, and evaluation of a patient before permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Interventional cardiology procedures where pacing is required

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISICS WITH PREDICATES

Intended Use

The subject device and predicate are external pulse generators intended to be used with a patient lead system to provide temporary, external cardiac pacing in a clinical environment. Solo Pace Control is designed primarily for interventional cardiology procedures that require controlled pacing. It is not intended to be used in a cardiac surgery/post operative situation. As such, reference to surgical procedures have been removed from the indications for use for the subject device. In addition, the use during procedures has been expanded to include interventional cardiology procedures.

Technological Features

Solo Pace Control is consistent in technological features to the Medtronic 5392 system in that it provides sensing and pacing. The design of the Solo Pace is simplified compared to the Medtronic device with only the features necessary for the single chamber pacing utilized in the catheterization laboratory for procedures requiring controlled pacing. The subject device has features of pre-sets organized around the framework of an interventional structural heart procedure, and ability to be controlled from within the sterile filed by the Bluetooth enabled RCM.

VII. PERFORMANCE DATA

Performance testing was performed in accordance with recognized international and domestic standards and FDA guidance documents. The performance verified the device design and materials through the following testing.

- System level verification testing
- Subsystem verification testing
- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Immunity with regard to intended use per IEC 60601-4-2
- Safety and performance of external pacemaker per IEC 60601-2-31
- Evaluation of wireless coexistence ANSI C63.27-2001 and AAMI C63.270-2021
- Software verification and validation
- Cybersecurity risk management and testing
- Package integrity testing to confirm sterility
- Shelf-life testing to confirm sterility and functionality
- Design validation with clinical users to validate user inputs and labeling

The results of the above performance testing met the specified acceptance criteria and demonstrate that differences in technological characteristics did not raise new safety or performance issues. Therefore, the Solo Pace Control described in this submission result in a device that is substantially equivalent to the predicate.

VIII. CONCLUSION

In conclusion, the Solo Pace Control is substantially equivalent to the commercially available predicate for its intended use as demonstrated by the performance data for the subject device.