June 12, 2026

Micropace Pty Ltd
℅ Amy Oakes
Regulatory Consultant
Acorn N Oakes LLC
333 N. Dobson Rd VO5
Chandler, Arizona 85224

Re: K253088
Trade/Device Name: OneStim-DUO Cardiac Stimulator (MP5003-4CO)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, JOQ
Dated: May 13, 2026
Received: May 14, 2026

Dear Amy Oakes:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), . Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for: MARCO CANNELLA -S

Aneesh Deoras
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K253088

Device Name

OneStim-DUO Cardiac Stimulator (MP5003-4CO)

Indications for Use *(Describe)*

The OneStim is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record cardiac electrical signals combined with a programmable diagnostic cardiac stimulator intended to be used for testing of the heart during cardiac electrophysiological studies and related procedures in hospital facilities.

The OneStim indicated for adult and pediatric population in the management of cardiac arrhythmias and conduction disorders.

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

The 510(k) Summary was drafted in accordance with 21 CFR 807.92 and is included below.

510(k) Information			
510(k) Number	K253088		
510(k) Type	Traditional 510(k)		
Date Prepared	11 June 2026		
Submitter Information			
Applicant	MicroPace Pty Ltd Unit 41, 159 Arthur Street, Homebush West, NSW 2140, Australia Dr. Michael Cejnar m.cejnar@micropace.com.au		
Correspondent	Acorn N Oakes LLC 333 N. Dobson Rd VO 5 Chandler, AZ 85224 United States Ms. Amy Oakes acornnoakes@cox.net		
Device Information			
Trade Name	OneStim-DUO Cardiac Stimulator (MP5003-4CO)		
Common Name	Programmable Diagnostic Computer		
Class	II		
Classification Name	Computer, Diagnostic, Programmable		
Product Codes	DQK, JOQ		
Predicate Devices	K083266	EP-Tracer System	DQK
	K011826	EPS320 Cardiac Stimulator	JOQ
Device Description Summary			

The OneStim Cardiac Stimulator is an updated portable addition to the Micropace EPS320 family of computerised diagnostic cardiac stimulators. It is for use by specialised cardiologist physicians in hospital electrophysiology (EP) laboratories and procedure rooms.

The OneStim Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachy-arrhythmias, refractory measurements and measurements of electrical conduction. The device is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart. The OneStim is a diagnostic device that is not intended for life supporting pacing, is not sterile, and has indirect intra-cardiac contact with patient (e.g. via third party catheters).

The OneStim is compatible with typical EP laboratory equipment such as EP recorders, ablation equipment, and 3D mapping systems. The device is suitable for use in hospital settings including EP

laboratories, X-ray procedure rooms, operating theatres and high dependency wards like ICU / CCU / ER.

The device is a laptop-sized console that can be powered by either mains or battery. It features a 12.1" LCD touch graphical user interface and a Patient Connection Box with shrouded 2mm sockets for connecting to 3rd party cardiac stimulation catheters and a 5 or 12 lead ECG patient cable.

An embedded IMx6 Windows CE computer provides graphical user control and directs multi-microprocessor controlled hardware.

The device provides up to four isolated pulse generator channels delivering pulses of up to 25mA and 20ms duration for intra-cardiac, epicardial or trans-oesophageal stimulation at intervals of between 30ms and 5000ms. The device registers electrograms from each stimulation channel, from external inputs and displays them with 5 or 12 lead surface electrograms on a graphical display for stimulus synchronisation and cardiac conduction measurements.

A PCCP is included with planned modifications to the OneStim including hardware and software modifications to provide a subset of functionality, updated GUI layouts, tactile user interface, and user selectable filtering for specific clinical procedures within the Intended Use.

These changes will be identified under new model numbers as indicated on the device labeling and IFU.

Indications for Use

The OneStim is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record cardiac electrical signals combined with a programmable diagnostic cardiac stimulator intended to be used for testing of the heart during cardiac electrophysiological studies and related procedures in hospital facilities.

The OneStim indicated for adult and pediatric population in the management of cardiac arrhythmias and conduction disorders.

Indications for Use Comparison

The subject device has the same indications for use as the predicate devices.

Technological Comparison

The OneStim device is a portable version of the EPS320 family of products previously cleared under K011826/K077220 using the same technological characteristics as the existing product line.

As a portable device the physical dimensions of the OneStim are similar to the EP-Tracer (K083266) and includes both battery modes (EP-Tracer) and mains power mode (EPS320).

The OneStim has the capability of displaying an ECG readout similar to the EP-Tracer.

Under the PCCP, a series of models each limited to a subset of the OneStim functionality specific to a given clinical procedure type will be released. In addition, updates to the OneStim design to

provide tactile feedback and user selectable filtering along with the existing raw data display will provide improved dynamic range, resolution, and CMRR.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following non-clinical bench tests were performed to assess the performance of the OneStim device.

- Physical and Mechanical Verification
- Chemical / Material Characterization
- Radiation Safety
- Usability in accordance with IEC 62366:2015
- Functional (Greybox) Performance testing used to evaluate the essential performance characteristics
- System Verification

No clinical data is being submitted with this application.

The following testing will be performed to validate the changes defined in the PCCP.

- Software Verification at unit, software and system level
- System Verification at the device and system level
- Hardware Verification at the device level

These validation activities will include :

- assessment on usability and labelling where applicable;
- confirmation that applicable risk controls remain effective and no unacceptable new risks have been introduced;
- review of supporting verification evidence against performance requirements (system bench testing, software testing, subsystem testing), traceability coverage of design inputs, and residual issues;
- final validation review and approval prior to market release.

The non-clinical performance (bench) testing demonstrates that the OneStim device meets the intended use and is substantially equivalent to the predicate devices. The device as modified by the PCCP will remain substantially equivalent to the predicate device.