July 30, 2026

Swift Sync Inc.
% Hrishikesh Gadakar, PhD
Senior Principal
RQM+
5000 Centregreen Way, Suite 100
Cary, NC 27513

Re: K252042
Trade/Device Name: Sync AV II Temporary Pacing Catheter
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: July 1, 2026
Received: July 2, 2026

Dear Hrishikesh Gadakar:

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 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,

JESSICA L. BATISTA -S

Digitally signed by JESSICA L. BATISTA -S
Date: 2026.07.30 17:37:17 -04'00'

Jessica Batista Bertolini
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.

510(k) Number *(if known)*
K252042

Device Name
Sync AV II Temporary Pacing Catheter

Indications for Use *(Describe)*
The Sync-AV II temporary pacing catheter is indicated for use in atrio-ventricular synchronic temporary intracardiac pacing for a maximum of three (3) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1 510(k) Summary

1.1 Contact Information

Sponsor/Manufacturer
Swift Sync Inc.
455 NE 91st Street
Miami Shores, FL 33138
Phone: 305-799-1435
Email: cmarinykall@swiftsync.net

Correspondent
Hrishikesh Gadagkar, Ph. D.
Regulatory Consultant,
RQM+
Phone: 410-245-0501
Email: hgadagkar@rqmplus.com

Date prepared: July 2, 2026

1.2 Device Information

Name of Device:	Sync AV II Temporary Pacing Catheter
Common or Usual Name:	Cardiovascular permanent or temporary pacemaker electrode
Classification Name:	Electrode, Pacemaker, Temporary
Regulation Number:	21 CFR 870.3680
Regulatory Class:	II
Product Code:	LDF

1.3 Predicate Device

BioTrace Tempo Temporary Pacing Lead (K160260)

1.4 Device Description

The Sync AV II Temporary Pacing Catheter (Sync AV II) consists of a single catheter with the following parts

- Outer Sheath
- Inner Sheath
- Atrial and Ventricular Leads

The Sync AV II is capable of atrio-ventricular synchronic pacing with a single catheter. It is introduced through an 8F introducer catheter to the heart through right jugular approach and has a Working length of 45.7 cm. The Sync AV II consists of an inner and outer shaft with 7 leads

contained within individual lumens of the Inner Sheath.

1.5 INDICATIONS FOR USE

The Sync-AV II Temporary Pacing Catheter is indicated for use in Atrio-Ventricular synchronic temporary intracardiac pacing for a maximum of three (3) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

1.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1-1: Device Comparison to the Predicate Device

Characteristic	**Swift Sync Pacing Catheter**	**Biotrace Tempo Lead (K160260)**
Intended Use	Intended for the temporary intracardiac pacing of the heart	Same
Indication for Use	The Sync-AV II Temporary Pacing Catheter is indicated for use in Atrio-Ventricular synchronic temporary intracardiac pacing for a maximum of three (3) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.	The BioTrace Medical Tempo Temporary Pacing Lead is indicated for use in temporary intracardiac pacing for a maximum of seven (7) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device
Product Code	LDF	Same
Lead Type	Temporary	Same
Lead Introduction Method	By cutdown or by use of a percutaneous catheter introducer or needle cannula	Same
Catheter Diameter	8F	6F
Number of Lumens	Seven (one for each electrode lead)	1

Characteristic	Swift Sync Pacing Catheter	Biotrace Tempo Lead (K160260)
Device Compatibility	Cannula or percutaneous introducer set to accommodate an 8F catheter	Cannula or percutaneous introducer set to accommodate an 6F catheter
Distal Configuration	Flexible, curved leads	Straight
Fixation	Passive, stabilized flexible stainless steel leads (3 arms in ventricle, 4 arms in atrium)	Active, stabilizer loops deploy into myocardium, and stabilizer balloon inflates to lodge the device into place
Lead Tip	Atraumatic	Same
Chamber Paced	Right Atrium and Ventricle	Right Ventricle
Lead Type	Unipolar	Bipolar
Number of Leads	Seven (7)	1
Number of Electrodes	Seven (3 ventricular, 4 atrial)	Two (2)
Single-use only	Yes	Same
Non-pyrogenic	Yes	Same
Biocompatibility	ISO 10993-1	Same

1.7 PERFORMANCE DATA

A high-level summary of the testing conducted to confirm the substantial equivalence of the Sync AV II Temporary Pacing Catheter is as follows:

- Dimensional
- Tensile
- Fatigue
- Continuity
- Hipot
- Torque
- Corrosion
- Sterile Barrier/Packaging Testing
- Electrical Safety

- EMC
- Shelf Life
- Biocompatibility
- GLP Animal Study
- Acute Clinical Study
- Human Factors Study

1.7.1 GLP Animal Study Overview

A single-arm GLP study was conducted to examine the safety and effects on tissue of the Sync AV II Temporary Pacing Catheter. 4 adult sheep had the Sync AV II placed under fluoroscopic guidance and paced for a total of 7 days before sacrifice. The device performance, local tissue response, gross necropsy, and histopathology were all evaluated. It was found that the Sync AV II demonstrated no safety concerns and performed as expected.

1.7.2 Clinical Study Overview

A single-arm, single site, non-randomized, prospective clinical study was conducted to evaluate the substantial equivalence of the Sync AV II Temporary Pacing Catheter. A total of 30 subjects needing temporary cardiac pacing were enrolled in the study.

The primary efficacy endpoint was ventricular pacing threshold at 24 hours post-implant. The average pacing threshold was 1.29V which met the predefined performance goal.

The primary safety endpoint was the incidence of serious procedural-related complications defined per the clinical protocol. The primary safety endpoint was met with no serious device-related complications.

Additional evaluations included:

- Atrial Pacing Threshold at 24 hours post-implant (powered)
- Successful placement of the device
- Pacing threshold prior to lead removal
- Sensing Amplitude and Pacing Impedance at 24 hours post-implant and prior to lead removal
- Dual chamber sensing and pacing through lead removal
- Incidence of lead dislodgement
- Incidence of lead fracture

1.8 SUBSTANTIAL EQUIVALENCE

Based on the same intended use, similar technological characteristics, and the summary of data submitted, the Sync AV II Temporary Pacing Catheter is found to be substantially equivalent to the predicate device. Safety and performance test data including bench testing, GLP animal study, electrical safety testing, and clinical study, demonstrated the device performed as intended without raising new and different questions of safety and effectiveness.