DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2016

St. Jude Medical
Blair Schwartz
Regulatory Affairs Specialist
14901 Deveau Place
Minnetonka, Minnesota 55345

Re: K161873
Trade/Device Name: Pacel™ Flow Directed Pacing Catheter
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: October 18, 2016
Received: October 19, 2016

Dear Blair Schwartz:

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 (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. 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.

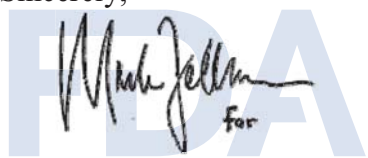
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161873

Device Name
Pacel™ Flow Directed Pacing Catheters

Indications for Use *(Describe)*
Pacel™ Flow Directed Pacing Catheters are indicated for use in temporary, transvenous, right ventricular pacing.

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 of the Pacel™ Flow Directed Pacing Catheters, per 21 CFR 807.92, is provided below.

510(k) Summary	
510(k) Number	**K161873**
Submitter Information:	
Date Prepared:	July 06, 2016
Submitter Name & Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 2182269
Contact Person:	Blair Schwartz Regulatory Affairs Specialist 5050 Nathan Lane N Plymouth MN 55426 Phone (651) 756-2706 BSchwartz@sjm.com
Device Information:	
Trade Name:	Pacel™ Flow Directed Pacing Catheters
Common Name:	Electrode, Pacemaker, Temporary
Class	II
Classification Name:	21CFR § 870.3680 – Cardiovascular permanent or temporary pacemaker electrode
Predicate Device:	Pacel™ Flow Directed Pacing Catheters (K914185)

510(k) Summary	
Device Description:	This catheter is designed to establish temporary right ventricular pacing with or without fluoroscopy guidance for placement. Catheters are depth marked as an aid in catheter placement under fluoroscopy. Electrodes at the catheter tip enable ECG monitoring and bipolar pacing. An inflatable balloon, located between two platinum electrodes, allows for flow directed positioning of the catheter in the right ventricle without fluoroscopy guidance. Once inflated, the balloon aids the operator in crossing the tricuspid valve. After the catheter has crossed the valve, the balloon is deflated and the catheter is advanced to the right ventricular apex in the usual manner. Electrograms are monitored to verify proper positioning in the right ventricular apex and pacing thresholds are obtained to confirm both proper location and reliable pacing. The catheters are available in two curve styles. The distal end of the catheter includes a platinum electrical connector ring and a tip electrode. The proximal end of the catheter includes a two pin electrical connector. The electrical signals can be transmitted to external equipment or from external equipment to the heart.
Intended Use: (Indications for Use)	Pacel™ Flow Directed Pacing Catheters are indicated for use in temporary, transvenous, right ventricular pacing.
Description of Change and Comparison to Predicate Devices	The Pacel™ Flow Directed Pacing Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the packaging, sterilization, final device specifications or labeling. The proposed change is to switch the current moisture cured cyanoacrylate adhesives, Loctite 4013 which is used to bond the latex balloon to the catheter and Loctite 4031 which is used to seal/trim around the metal electrode ring edges to a visible light cured cyanoacrylate adhesive, Loctite 4311.

510(k) Summary	
Summary on Non-Clinical Testing	Design Verification: Design verification testing has been completed for the Pacel Flow Direct catheter to show that the proposed device will meet Product Specification through the labelled Shelf Life of the device (T=18 mo). Design verification testing is complete and passed all acceptance criteria per the DV requirements. Testing Performed: • Surface Appearance: Adhesive on the balloon and electrodes. o Results: Conforming • Balloon Repeat Inflation Strength o Results: Conforming • Inflation Decay o Results: Conforming Biocompatibility: Biocompatibility testing was performed in accordance with ISO 10993. The proposed adhesive, Loctite 4311, used to secure the balloon to the catheter shaft demonstrated an acceptable biocompatibility profile. Biocompatibility testing passed all acceptance criteria. Chronic GLP Animal Study: Both the test and control devices were considered substantially equivalent regarding clinical pathology, thrombogenicity and pathology/histopathology. The use of both devices was well tolerated. This data demonstrates that the proposed Pacel Flow Direct catheter's safety is comparable to the control device.

510(k) Summary	
Statement of Equivalence	The Pacel™ Flow Directed Pacing Catheters that are subject of this application have the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device remains substantially equivalent to the predicate device.