



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

October 22, 2015

St. Jude Medical
Parita Mehta
Regulatory Affairs Specialist
14901 Deveau Place
Minnetonka, Minnesota 55345

Re: K152784

Trade/Device Name: Pacel Bipolar Pacing Catheters
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: September 24, 2015
Received: September 25, 2015

Dear Parita Mehta:

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

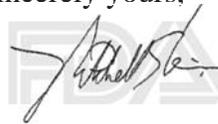
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 yours,



for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Pacel™ Bipolar Pacing Catheters

Indications for Use: The St. Jude Medical Pacel™ Bipolar Pacing Catheters are intended for use in the intracardiac pacing and/or ECG recording.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Premarket Notification 510(k)

510(k) Summary	
510(k) Number	To be Assigned
Submitter Information:	
Date Prepared:	September 24, 2015
Submitter Name & Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 2182269
Contact Person:	Parita Mehta Regulatory Affairs Specialist 5050 Nathan Lane N Plymouth MN 55426 Phone (651) 756-4442 Fax (651) 756-5744 PMehta@sjm.com
Device Information:	
Trade Name:	Pacel™ Bipolar Pacing Catheters
Common Name:	Electrode, Pacemaker, Temporary
Class	II
Classification Name:	21CFR § 870.3680 – Cardiovascular permanent or temporary pacemaker electrode
Predicate Device:	Pacel™ Bipolar Pacing Catheters (K875059)
Device Description:	The Pacel™ Bipolar Pacing Catheters are designed to establish temporary right ventricular pacing with fluoroscopy guidance for placement. Electrodes at the catheter tip enable ECG monitoring and bipolar pacing. The distal end of the catheter includes a stainless steel 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)	The St. Jude Medical Pacel™ Bipolar Pacing Catheters are intended for use in the intracardiac pacing and/or ECG recording.
Comparison to Predicate Devices	The Pacel™ Bipolar Pacing Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization, final device specifications or labeling. Biocompatibility and design verification (DV) testing demonstrate that the catheter shaft manufacturing process change does not adversely affect the device safety and effectiveness.

Premarket Notification 510(k)

Summary on Non-Clinical Testing	Biocompatibility testing was performed in accordance with ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. The catheters manufactured with the proposed new process met all the product performance specifications.
Statement of Equivalence	The Pacel™ Bipolar 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.