DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2014

St. Jude Medical, Inc.
Mr. Hassan Labay
Sr. Manager, Regulatory Affairs
776 Palomar Avenue
Sunnyvale, CA 94085

Re: K140793
Trade/Device Name: Nanostim Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 21, 2014
Received: November 24, 2014

Dear Mr. Labay:

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" (21CFR 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,

Kenneth J. Cavanaugh -S

for

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 on last page.

510(k) Number *(if known)*
K140793

Device Name
The Nanostim™ Introducer Kit

Indications for Use *(Describe)*
The Nanostim™ Introducer Kit is intended to provide a conduit into the venous system for insertion of diagnostic and other interventional devices.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"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."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name: St. Jude Medical, Inc.
Address: 667 Palomar Avenue
Sunnyvale, CA. 94085
Office: 650-404-5800

Contact Person: Hassan Labay
Phone Number: 408 522 6222
Facsimile Number: 650 404 2773

Date Prepared: 3/28/2014

Device Information:

Classification: Class II
Trade Name: St. Jude Medical Nanostim™ Introducer Kit
Common name: Introducer, Catheter
Classification name: Catheter Introducer (21 CFR 870.1340/DYB)

Predicate Devices:

The St Jude Medical Nanostim Introducer Kit is substantially equivalent in intended use and method of operation to the cleared Medtronic Mirca Introducer (K132030) and Medtronic Sentrant Introducer Sheath (K123990).

Device Description:

The St Jude Medical Nanostim Introducer Kit is designed to perform as a guiding sheath for introduction of diagnostic and interventional devices. The Nanostim™ Introducer Kit is comprised of an Introducer sheath and a dilator. The Introducer Kit is compatible with 0.035" and 0.038" guidewires and is available in 18F and one length of 30 cm. The introducer sheath is fitted with a hemostasis valve to prevent blood loss and minimize air introduction during introducer insertion and/or exchange. A sideport with a three-way stopcock is provided for air or blood aspiration and fluid infusion. The introducer features a radiopaque tip marker incorporated within the sheath material to identify the location of the distal tip of the sheath.

Intended Use:

The Nanostim™ Introducer Kit is intended to provide a conduit into the venous system for insertion of diagnostic and other interventional devices.

Summary of Technological Characteristics in Comparison to Predicate Device:

The St Jude Medical Nanostim Introducer Kit and the predicate devices (Medtronic Micra Introducer (K132030) and Sentrant Introducer Sheath (K123990)) have similar indication for use, technological characteristics and performance. Both the subject device and the predicate devices are designed to provide a conduit for delivery of diagnostic and other interventional devices. The minor differences in wording for intended use statements of the respective products do not alter the intended patient or clinical effect, and, therefore, the Nanostim Introducer Kit is substantially equivalent with respect to intended use. In addition, the minor differences in length and size do not present any new issues of safety or effectiveness. Moreover, performance testing demonstrates that the Nanostim Introducer Kit performs in a substantially equivalent manner.

Summary of Non-Clinical Testing:

Design verification and validation testing was performed to ensure that the Nanostim Introducer Kit met design specifications and customer requirements. Testing activities includes:

- Visual test
- Dimensional measurement test
- Tensile test
- Leak Test
- Liquid leakage under pressure (flow rate test)
- Side Port Torque

Biocompatibility Testing:

Biocompatibility testing for the Nanostim Introducer Kit has been completed in accordance with the International Standard IS0-10993-1:2009 "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing" for an external communicating device with limited exposure (contact with circulating blood is <24 hours).

Summary of Clinical Testing:

Clinical evaluation is not required for the Nanostim Introducer Kit.

Substantial equivalence:

The results of bench testing and compliance with applicable standards provide reasonable assurance that the Nanostim Introducer Kit has been designed and tested to assure conformance to the requirements for its indications for use.

St Jude Medical considers the Nanostim Introducer Kit to be substantially equivalent to the legally marketed predicate devices because it has similar intended use and similar indications, technological characteristics and performance. The minor differences between the subject device and the predicate devices do not alter the intended patient or clinical effect and, therefore, the Nanostim Introducer Kit is substantially equivalent to currently marketed predicate devices.