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

May 19, 2016

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

Re: K161102
Trade/Device Name: Nanostim Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 18, 2016
Received: April 19, 2016

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" (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,

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 below.

510(k) Number *(if known)*
K161102

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)

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

This summary of 510(k) substantial equivalence 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:	645 Almanor Avenue Sunnyvale, CA. 94085 Office: 408 522 6622
Contact Person:	Hassan Labay
Phone Number:	408 522 6622

Date Prepared: 4/18/2016

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 modified Nanostim Introducer Kit is substantially equivalent in intended use and method of operation to the predicate Nanostim Introducer Kit (K160716).

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 one size (18F) and two lengths (30cm and 50cm).

The introducer is fitted with a hemostasis valve to minimize air introduction during insertion and/or exchange, and a sideport with a three-way stopcock. The introducer features a radiopaque tip marker incorporated within the sheath material to identify the location of the distal tip of the sheath. Design modifications were made to the length and packaging of the current device. The changes made to the Nanostim Introducer Kit do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Indications For 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 modified device and the predicate device (K160716) have the same indication for use, technological characteristics and performance. Both the subject device and predicate device are intended to provide a conduit into the venous system for insertion of diagnostic and other interventional devices. The modified device is identical to the existing Nanostim Introducer Kit, with the exception of the device length. The predicate device is 30cm while the modified device is 50cm. The modification described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device, and, therefore, the subject device is substantially equivalent to the predicate device with respect to indications, design, and function.

Summary of Non-Clinical Testing:

Design verification testing was performed to verify the modified device remains substantially equivalent to the predicate device. Testing performed on the modified device included the following:

- Visual test;
- Dimensional measurement test;
- Torsional Strength;
- Simulated use/kink test

All of the pre-determined acceptance criteria were met.

Summary of Clinical Testing:

Clinical evaluation is not required for this device.

Substantial equivalence:

The subject device has the following similarities to the predicate device cleared under K160716:

- the same indication for use;
- the same fundamental scientific technology;
- the same technological characteristics;
- the same materials
- the same principles of operation;
- incorporates the same basic introducer design and has the same sterilization process;

The changes made to the device do not affect the intended use of the device or clinical effect and scientific technology of the device, therefore, the subject device is substantially equivalent to currently cleared Nanostim Introducer Kit 30cm (K160716).

Summary:

In summary, the modified device that is subject to this submission is substantial equivalent to the predicate device. It has the same indication for use, the same technological characteristics, the same materials, the same sterilization process and the same principles of operation as the predicate device. The differences between the modified device and the predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the subject device performs as the predicate device and is therefore substantially equivalent to the predicate device.