July 20, 2018

St Jude Medical
Rebecca Brunson
Regulatory Affairs Specialist
6901 Preston Road
Plano, Texas 75024

Re: K181382
Trade/Device Name: Guardian™ Burr Hole Cover System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: May 23, 2018
Received: May 25, 2018

Dear Ms. Brunson:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181382

Device Name
Guardian Burr Hole Cover System

Indications for Use *(Describe)*
The Guardian burr hole cover system is intended for use following cranial surgery as an implantable 14-mm (0.55-in) burr hole cover for the skull. It can also be used to secure a lead with a 1.29-mm (0.051-in) or 1.39-mm (0.055-in) diameter.

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

510(k) Summary	
510(k) Number	**K181382**
Submitter Information:	
Date Prepared:	May 23, 2018
Submitter Name & Address:	St. Jude Medical 6901 Preston Road Plano, TX 75024 USA
Contact Person:	Rebecca Brunson Regulatory Affairs Specialist Phone (972) 526-4658 Fax (855) 902-0767 Becky.Brunson@abbott.com
Device Information:	
Name of Device	Guardian ™ Burr Hole Cover System
Common Name:	Cover, Burr Hole
Regulatory Class	II
Classification Name:	882.5250 Burr Hole Cover
Predicate Device:	K152342: Guardian™ Burr Hole Cover System
Purpose of Submission	This Abbreviated 510(k) premarket notification is submitted to obtain clearance for the modification to the device labeling for the Guardian Burr Hole Cover System to include the "MR Conditional" statement in accordance with the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment".
Device Description:	The Guardian™ burr hole cover system is used to close a cranial burr hole and secure an implanted, compatible lead, when applicable. The burr hole cover system is nonpyrogenic and has three main features: base, clip, and cover. The base is intended for burr holes with a 14-mm (0.55-in) diameter. It contains two grooved slots to hold a lead in place. The clip fits into the base to hold the lead. The locking mechanism temporarily holds a lead in place before the burr hole cover is secured. The cover snaps onto the base, closing the burr hole and locking a lead in place.
Intended Use: (Indications for Use)	The Guardian™ burr hole cover system is intended for use following cranial surgery as an implantable 14-mm (0.55-in) burr hole cover for the skull. It can also be used to secure a lead with a 1.29-mm (0.051-in) or 1.39-mm (0.055-in) diameter.

Summary on Non-Clinical Testing	Non-clinical testing following the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", demonstrated that the Guardian™ Burr Hole Cover System is "MR Conditional".
Statement of Equivalence	The Guardian™ Burr Hole Cover System is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. The difference, the MR Conditional labeling, is supported by performance data. Based on the indications for use, technological characteristics, and the summary of data submitted, St. Jude Medical has determined that the proposed device is substantially equivalent to the currently marketed predicate device.