



Food and Drug Administration  
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Silver Spring, MD 20993-0002

June 9, 2016

St. Jude Medical  
Ms. Manasi Khare  
Senior Regulatory Affairs Specialist  
6901 Preston Road  
Plano, Texas 75024

Re: K152342  
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 6, 2016  
Received: May 9, 2016

Dear Ms. Khare:

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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152342

Device Name

Guardian™ Burr Hole Cover System

Indications for Use (Describe)

The Guardian™ Burr Hole Cover System is intended for use during cranial surgery as an implantable 14 mm 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

The 510(k) Summary of the Guardian™ Burr Hole Cover System, per 21 CFR 807.92, is provided on the following pages.

<b>510(k) Summary</b>	
510(k) Number	K152342
<b>Submitter Information:</b>	
Date Prepared:	August 17, 2015
Submitter Name & Address:	St. Jude Medical 6901 Preston Road Plano TX 75024 USA
Contact Person:	Manasi Khare Senior Regulatory Affairs Specialist Phone (818) 493-2085 MKhare@sjm.com
<b>Device Information:</b>	
Trade Name:	Guardian™ Burr Hole Cover System
Common Name:	Cover, Burr Hole
Class	II
Classification Name:	882.5250 Burr Hole Cover
Predicate Device:	NeuroPace, Inc. Burr Hole Cover (K123163) and (K141368)
Device Description:	<p>The Guardian™ burr hole cover system consists of three main features: base, clip, and cover. The Guardian™ burr hole cover system is used to close a cranial burr hole and can be used to secure an implanted compatible lead (1.29mm and 1.39mm). The burr hole cover is mated with the burr hole that is drilled in the patient's skull during the cranial surgery. The burr hole cover acts as a physical barrier protecting the exposed brain by covering the burr hole. The burr hole cover can also be used to provide temporary and permanent lead fixation.</p> <p>There are ancillary components of the system (base holder with cranial screws, clip, insertion tool and screw driver) that aid in the placement of the burr hole cover system. The base holder is intended to align the base with the burr hole and to maintain the cranial screws in place in the package and during installation.</p> <p>A clip insertion tool is intended to actuate the clip/insert and place it in the base. A screw driver is used to install the screws to the skull.</p>
Intended Use: (Indications for Use)	The Guardian™ Burr Hole Cover System is intended for use during cranial surgery as an implantable 14 mm 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.

Comparison to Predicate Devices

The Guardian™ Burr Hole Cover System has substantially equivalent intended use and fundamental scientific technology as the predicate device. The technological characteristics of the Guardian™ Burr Hole Cover System are substantially equivalent to the predicate device.

The design comparison between the Guardian™ Burr Hole Cover System and the predicate device indicate dimensional differences in the burr hole and lead compatibility that does not affect the device intended use of covering a hole in the cranium, as confirmed by the pre-clinical testing. The minor dimensional design difference between the Guardian™ Burr Hole Cover System and the predicate device is not imperative to establish the performance equivalence between the two systems.

The Guardian™ Burr Hole Cover System includes an ancillary clip which can be used for temporary restraint of the lead. The predicate device cover allows for both temporary and permanent restraint of the lead, so this does not introduce new issues of safety and effectiveness.

Both use Polyaryletheretherketone (PEEK) as the main material for the Burr Hole Cover. All the other additional materials do not affect the substantial equivalence and intended use of the device due to contact type or duration. Both the devices are single use and are sterilized using Ethylene oxide (EO).

A table has been added to capture the comparison between the Guardian™ Burr Hole Cover System and the predicate device:

Attribute	NeuroPace, Inc. Burr Hole Cover (K123163 and K141368)	Guardian™ Burr Hole Cover System (this application)
Indications for Use	Intended to cover a 14 mm burr hole following cranial surgery. Secondly, the NeuroPace Burr Hole Cover can be used to support 1.3 mm indwelling leads.	Intended for use during cranial surgery as an implantable 14 mm 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.
Anatomical Site	Permanent implant in cranium (skull)	
Burr Hole Compatibility	As produced by a 14 mm cranial burr. Minimum depth 2.7 mm	As produced by a 14 mm cranial burr. Minimum depth 3.7 mm
Lead Compatibility	1.3 mm diameter ± 0.05 mm	1.39 mm leads and 1.29 mm leads only
Main Components	Base, bone screws and cap	Base, clip, cover, and screws
Sterility	Sterile, single use	
Sterilization method	Ethylene oxide (EO)	
Labeled as non-pyrogenic	Yes	
Materials of Construction	Polyaryletheretherketone (PEEK) and silicone	Polyaryletheretherketone (PEEK);MP35N (Springs in insert), and titanium alloy (pins in insert); polycarbonate, silicone
Biocompatible	Yes	
Shelf Life	1 year	2 years

Based on the information in this premarket notification, the subject device has been shown substantially equivalent to the predicate device.

Summary on Non-Clinical Testing for the Guardian™ Burr Hole Cover System	Performance bench testing and biocompatibility testing were performed to verify the device met the pre-determined acceptance criteria and to confirm substantial equivalence. The following performance bench tests were performed:		
	Test	Testing Scope and Rationale	Results
	Preconditioning and Accelerated Aging	The SJM Burr Hole Cover (BHC) was preconditioned prior to subsequent pre-clinical testing.	All SJM devices preconditioned
		The NeuroPace Burr Hole Cover (BHC) was not preconditioned because final finished sterilized product was obtained from manufacturer and tested.	
	Hand-held Tool Drop/Shock Preconditioning	Only the SJM BHC was tested to confirm actuation of temporary restraint (with the insert) when using the handheld tool.	All SJM devices passed
		The NeuroPace BHC not tested because it doesn't have handheld tool.	
	Insert Lead Restraint Testing	Only the SJM BHC was tested to confirm that the lead can be temporarily restrained by the insert.	All SJM devices passed
		The NeuroPace BHC was not tested because it doesn't have an insert or temporary restraint mechanism.	
	Insert Rotation Testing	Only SJM BHC was tested to confirm that the insert does not rotate during temporary restraint.	All SJM devices passed
		The NeuroPace BHC was not tested because device doesn't have an insert or temporary restraint mechanism.	
Stylet/Guide Tube Removal	Only the SJM lead was tested to confirm the ability to remove a stylet, cannula, or guide tube when the insert (temporary restraint mechanism) is engaged.	All SJM devices passed	
	The NeuroPace leads were not tested because device doesn't have an insert or temporary restraint mechanism.		
Insert Multiple Actuation Testing	Only the SJM BHC was tested to confirm that the insert (temporary restraint mechanism) can be actuated multiple times.	All SJM devices passed	
	The NeuroPace BHC was not tested because it doesn't have an insert or temporary restraint mechanism.		
Cover Restraint Testing (after Worst Case Vibration)	Both SJM and NeuroPace BHC were tested after worst case vibration levels since they both have permanent restraint mechanisms (i.e. a cover).	All SJM and NeuroPace devices passed, confirming substantial equivalence of the devices	
Lead Electrical and Mechanical Damage	Only SJM lead was tested to confirm there would be no damage. The NeuroPace lead performance was not evaluated.	All SJM devices passed	
Vibration Testing	Only SJM BHC was tested to confirm performance at a pre-specified vibration level (separate from worst-case testing).	All SJM devices passed	

		The NeuroPace BHC was only tested at the worst-case vibration levels.	
	Cover Shear Testing	<p>Only the SJM BHC was tested to confirm performance during an application of shear force.</p> <p>The NeuroPace BHC was not tested because the system does not have a cover that can be subjected to shear forces.</p>	All SJM devices passed
	Insert/Base Interaction Testing	<p>Only the SJM BHC was tested to confirm the temporary restraint mechanism (the insert) is resistant to removal once engaged.</p> <p>The NeuroPace BHC was not tested because it doesn't have an insert.</p>	All SJM devices passed
	Affixation Check after Worst Case Vibration	Both SJM and NeuroPace BHC were tested to confirm the ability to permanently remain fixated to the mounting surface after worst case vibration levels.	All SJM and NeuroPace devices passed, confirming substantial equivalence of the devices
	Biocompatibility Cytotoxicity	<p>Only the SJM BHC system was assessed for potential cytotoxic effects, based on using an in vitro mammalian cell culture test. The study was conducted following the guidelines of ISO 10993-5.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 10993-5
	Biocompatibility Intracutaneous Reactivity	<p>Only the SJM BHC system was assessed for the potential to cause irritation, based on intracutaneous injection in rabbits. This study was conducted based on ISO 10993-10.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 10993-10
	Biocompatibility Sensitization	<p>Only the SJM BHC system was assessed for the potential to cause delayed contact dermal sensitization, based on the guinea pig maximization test. This study was conducted based on ISO 10993-10.</p> <p>The NeuroPace device was not tested.</p>	The SJM BHC system demonstrated compliance to ISO 10993-10

		The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.	
	Biocompatibility Acute Systemic Toxicity	<p>Only the SJM BHC system was assessed for the potential to cause acute systemic toxicity, based on the mouse injection test. This study was conducted based on ISO 10993-11.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 10993-11
	Biocompatibility Pyrogenicity	<p>Only the SJM BHC system was assessed for the potential to cause a pyrogenic response, based on the materials mediated rabbit pyrogen test. This study was conducted based on ISO 10993-11.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 10993-11
	Biocompatibility Particulate	<p>Only the SJM BHC system was assessed for the particulate load, based on the light obscuration method. This study was conducted based on ISO 14708-3, particulate load.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 14708-3
	Biocompatibility Chemical Characterization	<p>Only the SJM BHC system was assessed for chemical characterization per ISO 10993-18 to demonstrate that the leachables are toxicologically acceptable per ISO 10993-17.</p> <p>The NeuroPace device was not tested.</p> <p>The SJM BHC and the predicate device are classified in the same device category based on body contact and contact duration and were also assessed for compliance to the same ISO standard; therefore evaluation of the NeuroPace predicate is not required.</p>	The SJM BHC system demonstrated compliance to ISO 10993-18 and ISO 10993-17

	Sterilization and Sterility	<p>The SJM and Neupace BHC are sterilized as per ISO 11135:2007 (Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices) and the EO residuals were evaluated as per ISO 10993-7:2008 (Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals).</p> <p>Since, both these devices have proved compliance to these standards, further evaluation of the NeuroPace BHC was not deemed necessary.</p>	All SJM devices passed, demonstrating compliance to the same ISO standard and confirming substantial equivalence of the devices
Statement of Equivalence	The Guardian™ Burr Hole Cover System has 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 and predicate device has been shown to be substantially equivalent.		