March 13, 2020

NeuroVention, LLC
Rohit Khanna
President
645 S. Beach St.
Daytona Beach, Florida 32114

Re: K192162
Trade/Device Name: NeuroVention Cranial Fixation System, NuCrani Plates, KTC Burr Hole Cover, DC Plate
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR, GWO, HBW
Dated: February 11, 2020
Received: February 12, 2020

Dear Rohit Khanna:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K192162

Device Name

NeuroVention Cranial Fixation System

Indications for Use *(Describe)*

The NeuroVention Cranial Fixation System is intended for use as a burr hole cover and/or skull bone fixation following craniotomy, cranioplasty, or craniectomy surgery.

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.

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510(k) Summary

(as required by 21 CFR 807.92)

Submitter	NeuroVention LLC
Address	645 S Beach Street Daytona Beach, FL 32114
Telephone	386-238-9638
Fax	386-253-8174
Contact Person	Rohit Khanna, M.D.
email	khanna@neurovention.com
Date Prepared	January 27, 2020
Trade Name	Neurovention Cranial Fixation System Includes: NuCrani Plates, DC Plate, and KTC burr hole cover
Common Name	Neuro plating system
Panel Code	Neurological Devices
Classification Name	Burr Hole Cover (GXR) Preformed Alterable Cranioplasty Plate (GWO) Cranioplasty Plate Fastener (HBW) Drills, Burrs, Trephines & Accessories- Manual (HBG)
Class	Class II
Regulation Number	21 CFR 888.5250 21 CFR 888.5320 21 CFR 888.5360 21 CFR 882.4300
Product Code	GXR, GWO, HBW, HBG

Predicate Device Name	**510(k) Number**	**Manufacturer**
Stryker Universal Neuro 3 System	K112557	Stryker

Description

The NeuroVention Cranial Fixation System is a series of burr hole covers and plates with various configurations to facilitate surgeon selection of the implant he/she determines to be most appropriate for the patient and the surgical circumstances. Each is provided non-sterile single use and is made of titanium as per ASTM F67, titanium alloy (Ti-6Al4V ELI) implantable components that comply with ASTM F136 or PEEK per ASTM F2026. Class I exempt instrumentation is available for delivery and removal: Screwdriver Adapter (handle), Torx Drivers, Forceps. Additionally, a Class II Drill bit is included to create pilot holes for the screws.

Indications and Intended Use

The NeuroVention Cranial Fixation System is intended for use as a burr hole cover and/or skull bone fixation following craniotomy, cranioplasty, or craniectomy surgery.

Technological Characteristics and Substantial Equivalence

Documentation was provided to demonstrate that the NeuroVention Cranial Fixation System is substantially equivalent to the legally marketed predicates. It consists of a storage module that contains the various shapes of implants, screws and implantation instruments. The devices and accessories included in the Subject device and the predicate devices are both burr hole covers, cranioplasty plates and screws. The NeuroVention Cranial Fixation System is substantially equivalent to the predicate devices in intended use, site of application, patient population, conditions of use, mechanical performances, basic design, and operating principles. The NeuroVention Cranial Fixation System is comparable to its predicate in size and materials. Mechanical testing shows the mechanical strength of the Subject device to be equivalent or better than the predicate devices.

	NeuroVention Cranial Fixation System	**Stryker Universal Neuro 3 System**		
Manufacturer	NeuroVention	Stryker		
510(k) number	This application	K112557		
Product Code	GXR, GWO, HBW	GXR, GWO, HBW		
Classification Regulation	21 CFR 882.5250, 882.5320, 882.5360	21 CFR 882.5250, 882.5320, 882.5360		
Common Name	Burr Hole Cover, Preformed Alterable Cranioplasty Plate, Cranioplasty Plate Fastener	Burr Hole Cover, Preformed Alterable Cranioplasty Plate, Cranioplasty Plate Fastener		
Class	II	II		
Implantable components	Yes	Yes		
Anatomic Locations	Skull	Skull		
Intended Use	Cover burr holes and skull bone fixation following craniotomy, cranioplasty, or craniectomy surgery.	Cover burr holes and skull bone fixation following craniotomy, cranioplasty, or craniectomy surgery.		
Indications for Use Statement	The NeuroVention Cranial Fixation System is intended for use as a burr hole cover and/or skull bone fixation following craniotomy, cranioplasty, or	The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization, and/or rigid fixation of non-loadbearing areas subsequent to craniotomy, craniectomy, and cranial fractures		

	craniectomy surgery.	n adults and adolescents (age 12 and higher).		
Implant Material	Titanium, Titanium alloy (Ti6AL4V ELI) PEEK (VESTAKEEP) per ASTM F2026	Titanium, Titanium alloy (Ti6AL4V ELI)		
Instrument materials	Stainless Steel	Stainless Steel		
Sterilization	Provided non-sterile to be steam sterilized by user facility	Provided non-sterile to be steam sterilized by user facility		
MRI compatibility	Non-clinical testing has demonstrated the NeuroVention Cranial Plate System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: • Static magnetic field of 1.5 T and 3.0 T; • Maximum spatial field gradient of 6,200 G/cm (62 T/m); • Quadrature driven, Circular Polarized (CP) Mode Only • Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (Normal Control Mode). • Maximum Head SAR of 3.2 W/kg. Under the scan conditions defined above, the NeuroVention Cranial Plate System is expected to produce a maximum temperature rise of less than 2.5 ºC after 15 minutes of continuous scanning at 1.5 T and less than 3.5 ºC after 15 minutes of continuous scanning at 3.0 T. In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the NeuroVention Cranial Plate System when imaged with a gradient echo pulse sequence and a 3 T MRI system.	“has not been evaluated for safety and compatibility in the MR environment” and that it “has not been tested for heating or migration in the MR environment.”		

Name of Device	NeuroVention Cranial Fixation System	Stryker Universal Neuro 3 System
Implant Size Ranges	• NuCrani Small Rectangular 4 hole plate, 12 x 20 mm • NuCrani Medium Circular 8 hole plate • NuCrani Large Circular 7 hole Plate, 20 x 27 mm • KTC Burr Hole Cover 26.5 mm • DC plate, 15 x 24 mm • 2.0mm Self Tapping Screws, 6-10 mm • 2.3 mm Self Tapping Rescue Screws, 6-10 mm	• 2 hole dogbone plate • Straight plate 2 hole • Straight plate 8 hole • Straight plate 16 hole • Double Y plate • Box plate 2x2 hole • Rectangle plate • X plate • Gap plate, small • Gap plate, large • Burr hole cover, 7mm • Burr hole cover, 10mm • Burr hole cover 14mm • Burr hole cover, 20mm • Burr hole cover, 24mm • Round malleable plate, 42-58 mm • Suboccipital malleable plate, 62 x 30 mm • Subocciptial malleable plate, 65 x 40 mm • Temporal malleable plate, 47 x 29 mm • Translabyrithine malleable plate, 54 x 52 mm • Translabyrinthine malleable plate, 60 x 60 mm • 1.5 mm Self Drilling Screws, 3-5 mm • 1.5 mm Self Tapping screws, 4-6 mm • 1.7 mm Emergency Screws, 4mm
Manual Drill Bit	1.5 mm diameter	1.2 mm diameter

Performance Data

The potential hazards have been evaluated and controlled through Risk Management.

All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicates. Clinical data was not needed to support the safety and effectiveness of the Subject Device.

The following mechanical testing was performed:

- Static Compression
- Skull Conformity
- Screw Axial Pushout
- Screw Torque to Failure per ASTM F543-13
- Usability testing of Drill Bit

All results passed acceptance criteria and were equivalent or better when compared to the predicates.

Biocompatibility

The components of the predicate device for the implantable components, are manufactured from the same titanium and titanium alloy for implantable components in conformity with ASTM F67-13 and ASTM F136. The Subject device also has a PEEK configuration made from VESTAKEEP by Evonik Industries per ASTM F2026. The instruments are made of the same stainless steel in conformance with ASTM F899. These materials are well known and well characterized have been used in other commercially available cranial implants. The predicate devices are used for the same duration and come into contact with the patient in the same manner and in the same body parts. The materials are considered to be biocompatible and have a long history of safe use as part of medical devices marketed in the United States and around the world. The Subject and predicate devices as well as a large number of implantable devices are manufactured in the same way with the same materials.

Conclusion

Based on design, materials, intended use, technological characteristics, and comparison to predicate devices, the Subject Neurovention Cranial Fixation System has been shown to be substantially equivalent to legally marketed predicate device.