DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 27, 2015

Alliance Partners, LLC
% Mr. Kellen Hills
Quality & Regulatory Consultant
Orchid Design, A Division of Orchid Orthopedic Solutions
4600 East Shelby Drive, Suite 1
Memphis, TN 38118

Re: K141123
Trade/Device Name: Alliance Spine RAAS Cranial Plating System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: February 20, 2015
Received: February 25, 2015

Dear Mr. Kellen Hills,

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

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)*
K141123

Device Name
RAAS Cranial Plating System

Indications for Use *(Describe)*
The Alliance Spine RAAS Cranial Plating System is indicated for osteotomies, craniotomy, cranial fractures, and reconstruction of non-load bearing cranial areas.

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]

(a)(1)	Submitted By:	Alliance Partners, LLC (dba Alliance Spine™) 14206 Northbrook Dr. San Antonio, TX 78232
	Date:	February 20, 2015
	Contact Person:	Tim M. Lohnes Senior Regulatory Consultant Orchid Design
	Phone:	203-922-0105
	Fax:	203-922-0130
(a)(2)	Proprietary Name:	RAAS Cranial Plating System
	Common Name:	Bone Plates, Bone Fixation Fasteners
	Classification Names and References:	882.5320 - Preformed alterable cranioplasty plate 882.5250 - Burr hole cover 882.3560 - Cranioplasty plate fastener
	Product Codes:	GWO, GXR, HBW
(a)(3)	Predicate Devices:	Stryker-NEURO II (K031659) OsteoMed-Low Profile Neuro (K111176)

(a)(4) Device Description:

The Alliance Spine RAAS Cranial Plating System consists of various sizes and geometries of malleable low profile cranial plates including straight, box, and gap plates, burr hole covers, malleable mesh as well as fasteners (screws) that provide stable internal fixation of cranial fractures and bone flaps, as well as coverage and stabilization of burr holes and other cranial defects.

The RAAS plates and burr hole covers are 0.5mm thick, while the RAAS malleable Mesh is supplied in 0.3mm and 0.6mm thickness. The fasteners (screws) are supplied in 1.5mm diameter Self-Drilling and 1.5mm diameter Self-Tapping configurations in 4mm and 5mm lengths, while the RAAS Rescue Screws are 1.7mm in diameter in 5mm and 6mm lengths. The Screws and Mesh are color anodized for identification.

(a)(5) Indications for Use:

The Alliance Spine™ RAAS Cranial Plating System is indicated for osteotomies, craniotomy, cranial fractures, and reconstruction of non-load bearing cranial areas.

(a)(6) Technological Characteristics:

	SUBJECT DEVICE	PREDICATE DEVICES	
Manufacturer	Alliance Spine	Stryker	OsteoMed
System Name	RAAS Cranial Plating System	Neuro 2 Cranial Plate System	Low Profile Neuro Fixation System
510(k)	Subject	K031659	K111176
Product Codes	GWO, GXR, HBW	JEY, HWC	GWO, GXR
Indications for Use	The RAAS Cranial Plating System is indicated for osteotomy, craniotomy, cranial fractures, and reconstruction of non-load bearing cranial areas.	The Stryker Leibinger Universal Neuro System is a low-profile plate and screw system intended for osteotomy, craniotomy, stabilization and rigid fixation of craniofacial fractures and reconstruction of non-load bearing areas.	The OsteoMed LowProfile Neuro Fixation System is indicated for use in ostemtomies, fractures or reconstruction of cranial bones. Implants and drills are single use only.
Sterilization	End User (steam)	Non-sterile and sterile	Not specified
Shelf Life	n/a	Not specified	Not specified
Implant Material: Plates and Burr Hole Covers – Mesh – Screws -	 ASTM F136 ASTM F67 ASTM F136	 CP Ti CP Ti Ti Alloy	 ASTM F136/F67 ASTM F136/F67 ASTM F136
Thickness: Plates & Burr Hole Covers – Mesh -	 0.5mm 0.3 and 0.6mm	 0.6 and 0.5mm 0.1, 0.2, 0.3 and 0.6mm	 0.25 to 1.0mm 0.25 to 1.0mm
Surface Treatment: Plates & Burr Hole Covers	None	Type III Anodized	Not specified
Surface Treatment: Mesh	Type III Anodized	Type III Anodized	Not specified
Screws – type	Self-tapping, drilling, and rescue	Self-tapping, drilling, and rescue	“Auto Drive” and rescue

Screws: diameter/length	1.5 x 4 & 5mm, 1.7 x 5 & 6mm	1.5mm x 4, 5 & 6mm 1.7mm x 4mm	1.6mm x 4, 5, 6 & 8mm, 1.9mm x 4, 5, 6 & 8mm
Surface Treatment: Screws	Type III Anodized	Type III Anodized	Not specified

(b)(1) Non-clinical testing:

Test	Test Method Summary	Results
Static Axial Compression	Worst case Burr Hole plates were subjected to loading as described in ASTM F382.	Peak load and stiffness values were acceptable based on intended use and predicate data. Subject device expected to perform similarly to predicate.
Insertion/Removal Torque	Worst case screws were inserted into and then removed from a test block as described in ASTM F543.	Driving torque values were acceptable based on intended use and predicate data. Subject device expected to perform similarly to predicate.
Ultimate Torque	Worst case screws were fixed below the head and subjected to loading as described in ASTM F543.	Peak torque values were acceptable based on intended use and predicate data. Subject device expected to perform similarly to predicate.
Axial Pullout	Worst case screws were inserted to a fixed depth and subjected to loading as described in ASTM F543.	Peak load values were acceptable based on intended use and predicate data. Subject device expected to perform similarly to predicate.

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification, we believe that the subject RAAS Cranial Plating System demonstrates substantial equivalence and has a safety and effectiveness profile that is similar to the identified predicate devices.