March 22, 2018

Alliance Partners, LLC
Kristiina Gilkey
QA/RA Manager
14206 Northbrook Drive
San Antonio, Texas 78232

Re: K173128
Trade/Device Name: Alamo® C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 16, 2018
Received: February 20, 2018

Dear Ms. Gilkey:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic 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)*

K173128

Device Name
Alamo® C

Indications for Use *(Describe)*

The Alamo® C is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with an intervertebral cage. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via an open, anterior approach.

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

5.1 Submitter

Company:	Alliance Partners, LLC (dba Alliance Spine) 14206 Northbrook Drive San Antonio, Texas 78232
Phone:	210-314-2525
Fax:	210-314-2524
Contact Person:	Kristiina Gilkey
Date Prepared:	March 21, 2018

5.2 Device

Name of Device:	Alamo® C
Common Name:	Intervertebral body fusion device, Cervical
Classification Name:	Intervertebral body fusion device (21 CFR 888.3080)
Regulatory Class:	Class II
Product Code:	ODP
Review Panel:	Orthopedic

5.3 Predicate Device

Primary Predicate:	Alamo® C [K133321 & K112361]
Additional Predicates:	Life Spine Small PLATEAU® (PLATEAU-C Ti) Spacer System [K161127] Rhausler Plage™ Anterior Cervical Fusion System [K111272] Alliance Partners Nakoma® ACP [K141993]

5.4 Reason for 510(k) Submission

The purpose of this submission is to expand the Alamo C Interbody Fusion System to include a version of intervertebral body fusion devices manufactured from titanium. This modification does not affect the device's intended used or alter the device's fundamental scientific technology.

5.5 Device Description

The Alamo C is designed for use as a cervical intervertebral body fusion device. The device is manufactured from either PEEK Optima® LT1 per ASTM F2026 with tantalum markers per ASTM F560 for radiographic visualization or titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

The profile of the device is rectangular with a hollow core for bone graft to promote bone integration and fusion between the vertebral end plates. The device is available in various axial footprints and heights to accommodate variability among patients and the inferior and superior surfaces are designed with ridges (teeth) to improve fixation and stability and prevent back out and migration.

5.6 Indications for Use

The Alamo C is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is

defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with an intervertebral cage. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via an open, anterior approach.

5.7 Comparison of Technological Characteristics with Predicate Device

The subject Alamo C has the same intended use and similar technological characteristics to the predicate Alamo C in terms of design, dimension, function, and performance characteristics. There are no significant differences between the devices which would adversely affect the use of the product.

Additionally, the subject Alamo C devices are fabricated from similar materials of construction as the predicate Small Plateau-C Ti device, Plage device, and Nakoma ACP device.

5.8 Performance Data / Non-clinical Tests

Performance testing was conducted on the subject Alamo C device in accordance with ASTM F2077, ASTM F2267, and ASTM Draft Standard F-04.25.02.02 to establish substantial equivalency with the predicate Alamo C device. Testing included static axial compression, dynamic axial compression, static torsion, subsidence, and expulsion. The results obtained demonstrate the subject Alamo C device functions as intended and is substantially equivalent to the predicate Alamo C device.

5.9 Clinical Tests

No clinical studies were conducted.

5.10 Conclusions

Submitted data demonstrates that the subject Alamo C device is substantially equivalent to the predicate devices with regard to intended use, indications for use, design, performance, materials and technological characteristics.