510(k) Summary

JAN - 9 2014

Submitted By:	Alliance Partners, LLC 14206 Northbrook Dr. San Antonio, TX 78232
Date:	January 7, 2014
Contact Person:	Jennifer Palinchik Regulatory Consultant
Contact Telephone:	(440) 933-8850
Device Trade Name:	Alamo C
Device Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Cervical
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3080
Product Code:	ODP
Predicate Device:	Alliance Partners, LLC Alamo C (K112361) Depuy Bengal System (K081917) Alphatec Spine Novel Spinal Spacer System (K081730)

Device Description:

The Alamo C is designed for use as a cervical intervertebral body fusion device. The device is manufactured from PEEK Optima® LT1 per ASTM F2026 and includes tantalum markers per ASTM F560 for radiographic visualization.

The device footprint has a hollow centre to accommodate bone graft to facilitate bone integration and fusion between the end plates from an anterior (ACIF) surgical approach. 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 to improve fixation and stability and prevent back out and migration.

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.

Substantial Equivalence Information:

The design features, material, manufacturing process, sterilization process, labeling, and indications for use of the subject device are identical to the previously cleared device except additional axial footprints have been added to the system. These additional sizes are substantially equivalent to the predicate devices listed above. The safety and effectiveness is adequately supported by the documentation provided within this Premarket Notification.

Mechanical Testing:

Performance testing was conducted to confirm the modification did not alter the worst case scenario of the device. Testing was performed in accordance with ASTM F2077. The device functioned as intended and the performance results show that the modified Alamo C is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

Alliance Partners, LLC
% Ms. Jennifer Palinchik
Regulatory Consultant
JALEX Medical, LLC
33490 Pin Oak Parkway
Avon Lake, Ohio 44012

Re: K133321
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: December 12, 2013
Received: December 13, 2013

Dear Ms. Palinchik:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133321

Device Name: Alamo C

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices