510(k) Summary

AUG 24 2012

Contact: Robert M. Wolfarth, CQA
Amedica Corp.
1885 West 2100 South
Salt Lake City, UT 84119
(801) 839-3500

Device Trade Name: Phantom Plus® Ceramic Cage System

Manufacturer: Amedica Corp.
1885 West 2100 South
Salt Lake City, UT 84119

Common Name: Intervertebral body fusion device

Classification: 21 CFR §888.3080

Device Class: II

Product Codes: MAX, ODP

Date Summary Prepared: June 28, 2012

Indications For Use:

The Phantom Plus Ceramic Cages-Lumbar are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six (6) months of nonoperative therapy.

The Phantom Plus Ceramic Cage System-Lumbar is to be filled with autogenous bone graft material. The Phantom Plus Ceramic Cages-Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System.

The Phantom Plus Ceramic Cages-Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Phantom Plus Ceramic Cages-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone.

The Phantom Plus Ceramic Cages-Cervical are to used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Device Description:
The Phantom Plus Ceramic Cage System consists of a variety of hollow vertebral body spacers featuring convex, bullet nose design and an axial void designed to hold bone graft material. The subject device is offered in various lengths. The subject devices are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 6mm to 22mm in height and 14mm to 45mm in length.

Predicate Device(s):
The Phantom Plus Ceramic Cage System was shown to be substantially equivalent to previously cleared devices, including itself (K082801) and the Valeo® Spacer System (K091278), and has the same or equivalent indications for use, design, function, and materials used.

Performance Standards:
Testing and engineering analyses on this device indicate that the Phantom Plus Cage System is substantially equivalent to predicate devices. ASTM F2077, ASTM F2267, ASTM F1839, ASTM F1877, ASTM F04.25.02.02, and AAMI TIR 33 performance standards were adhered to and all applicable requirements were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 2 4 2012

Amedica Corporation
% Mr. Robert M. Wolfarth
Director of Regulatory Affairs
1885 West 2100 South
Salt Lake City, Utah 84119

Re: K121892
Trade/Device Name: Phantom Plus® Ceramic Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 3, 2012
Received: August 8, 2012

Dear Mr. Wolfarth:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K121892

Device Name: Phantom Plus® Ceramic Cage System

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DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Phantom Plus Ceramic Cages-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone.

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121892