

510(k) Summary

Contact: Robert M. Wolfarth, CQA
Amedica Corporation
801-839-3500

JAN 28 2010

Device Trade Name: Valeo® Spacer System

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

Common Name: Intervertebral body fusion device

Classification: 29 CFR §888.3080

Class: II

Product Code: MAX, ODP

Indications For Use:

The Valeo Spacer System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. The device must be used with additional anterior or posterior instrumentation to augment stability.

The Valeo Spacer System -C is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Valeo Spacer System -C is to be used in patients who have had six weeks of non-operative treatment.

The Valeo Spacer System -AL, -TL, -PL, -XT are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Valeo Spacer System -AL, -TL, -PL, -XT is to be used in patients who have had six months of non-operative treatment.

Device Description:

The Valeo Spacer System consists of cervical and lumbar component spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Valeo Spacer System is manufactured from MC², a ceramic material, and is provided sterile.

Predicate Device(s):

The Valeo Spacer System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used.

Performance Standards:

Testing performed on this device indicates that the Valeo Spacer System is substantially equivalent to predicate devices. ASTM F2077 performance standards were adhered to and all applicable requirements were met.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 28 2010

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

Re: K091278

Trade/Device Name: Valeo® Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: January 21, 2010
Received: January 25, 2010

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

Page 2 - Mr. Robert M. Wolfarth, CQA

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): K091278

Device Name: Valeo[®] Spacer System

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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 K091278