



August 19, 2016

AMEDICA® Corporation
Mr. William D. Jordan
Senior Director, Regulatory Affairs & Quality Assurance
1885 West 2100 South
Salt Lake City, Utah 84119

Re: K161405

Trade/Device Name: Valeo II™ Interbody Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OPD
Dated: July 20, 2016
Received: July 21, 2016

Dear Mr. Jordan:

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 Parts 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" (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 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,

Lori A. Wiggins -S

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)

K161405

Device Name

Valeo II™ Interbody Fusion Device System

Indications for Use (Describe)

Valeo II Interbody Fusion Devices - 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 or two contiguous levels.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo II Interbody Fusion Devices-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Valeo II Interbody Fusion Devices-Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo II Interbody Fusion Devices-Lumbar are indicated for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous 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).

Valeo II Interbody Fusion Devices-Lumbar are intended to be used with supplemental spinal fixation systems. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) Summary

Device Trade Name: Valeo II™ Interbody Fusion Device System

Device Common Name: Interbody Fusion Device

Manufacturer: AMEDICA® Corporation
1885 West 2100 South
Salt Lake City, UT 84119
Phone: (855) 839-3500

Contact: William D. Jordan
Senior Director Regulatory Affairs

Date Prepared: May 19, 2016

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX, ODP

Primary Predicate: Valeo II™ Interbody Fusion Device (K121892)

Additional Predicates: Globus PATRIOT® TransContinental® Llif Spacer (K093242)
Valeo II™ Interbody Fusion Device (K143518)

Indications For Use:

Valeo II Interbody Fusion Devices - 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 or two contiguous levels.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo II Interbody Fusion Devices-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to C7-T1 disc space using autograft or allogenicbone graft comprised of cancellous and/or corticocancelous bone graft.

Valeo II Interbody Fusion Devices-Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo II Interbody Fusion Devices-Lumbar are indicated for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous 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).

Valeo II Interbody Fusion Devices-Lumbar are intended to be used with supplemental spinal fixation systems. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Device Description:

The Valeo II Interbody Fusion Devices consist of a variety of hollow intervertebral body spacers featuring convex, bullet nose design and an axial void designed to hold bone graft material (autograft or allograft comprised of cancellous and/or corticocancellous bone graft).

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 Valeo II Interbody Fusion Device is manufactured from Si₃N₄ ceramic material (silicon nitride), and is:

- provided sterile (gamma sterilization)
- single use

The purpose of the subject 510(k) is to add additional sizes to the Lateral Lumbar Interbody Fusion Device – Valeo II LL.

Predicate Device:

The Valeo II™ Interbody Fusion Device – Lumbar is substantially equivalent to the predicate Valeo II™ Interbody Fusion Device - Lumbar with respect to indications, design, performance and materials of manufacture. Additionally, the Valeo II™ Interbody Fusion Device – Lumbar is substantially equivalent to the Patriot Transcontinental Llif Spacer with respect to available configurations.

Performance Testing:

Failure Effects Analysis was performed to determine if the new sizes created a new worst case with respect to ASTM F2077 and ASTM F2267. No new worst cases were identified with regard to the ASTM standards requirements. No additional testing required.

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST-72:2011 confirm an endotoxin limit of 0.5EU/mL.

Guidance Referenced:

Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

Conclusion:

The Valeo II Interbody Fusion device has the same intended use, material of manufacture and is manufactured using the same processes. Performance evaluation demonstrates that the Valeo II Interbody Fusion Device is substantially equivalent to the predicate devices.