DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2016

Amedica Corporation
Ms. Shanna Ryan
Regulatory Affairs Project Manager
1885 West 2100 South
Salt Lake City, Utah 84119

Re: K162160
Trade/Device Name: Preference Elite Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: October 24, 2016
Received: October 25, 2016

Dear Ms. Ryan:

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 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" (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.

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,

Mark N. Melkerson -S

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)*
K162160

Device Name
Preference Elite Pedicle Screw System

Indications for Use *(Describe)*
The Preference Elite Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine as follows:

The Preference Elite System is intended for posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Preference Elite Pedicle Screw System is indicated for skeletally matures patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint, (b) who are receiving fusions using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (d) who are having the device removed after the development of a solid fusion mass.

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.

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Traditional 510(k) Summary

1. Submitted by: Amedica® Corporation
   1885 W 2100 S
   Salt Lake City, UT 84119
   Ph: 801-839-3562
   Fax: 801-839-3605

2. Contact: Shanna Ryan

3. Date of summary: October 24, 2016

4. Trade Name: Preference Elite Pedicle Screw System

5. Common Name: Pedicle Screw System

6. Product Code: NKB, MNH, MNI, KWP

7. Classification Regulation:
   21 CFR 888.3070

8. Class: III
9. Panel: Orthopedic

10. Predicate Device(s):

	510K	Trade Name	Product Code	Classification	Manufacturer
Primary	K081883	Preference Pedicle Screw System	MNH, MNI, NKB, KWQ, KWP	21 CFR 888.3070 21 CFR 888.3060 21 CFR 888.3050	US Spine (acquired by Amedica)
Additional	K073430	Valeo® PS Pedicle Screw System	NKB, MNH, MNI	21 CFR 888.3070	Amedica Corporation

11. Device Description

The Preference Elite Pedicle Screw System is a spinal fixation system consisting of a variety of components including screws, various types and sizes of rods, cross-connectors and accessories, as well as implant components from the Preference Pedicle Screw System. The components are designed to be rigidly locked into a variety of configurations with each construct being appropriate for the individual patient.

Implant components from the Preference Pedicle Screw System including the curved and straight rods, set-screws, and cross-connectors are compatible with the Preference Elite Pedicle Screw System.

The Preference Elite Pedicle Screw System implants and components are made from titanium alloy (Ti-6A1-4V) per ASTM F136 and Cobalt-28 Chromium-6 Molybdenum Alloy (Co-28Cr-6Mo) per ASTM F1537.

12. Purpose of 510k

    The purpose of this Traditional 510(k) is to seek clearance for the Preference Elite Pedicle Screw System. The Preference Elite Pedicle Screw System is a new system comprised of new implants, components and instruments, in addition to previously cleared implants and components in the Preference Pedicle Screw System.

13. Indications for use

    The PREFERENCE ELITE Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine as follows:

    The PREFERENCE ELITE System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

    In addition, when used as a pedicle screw fixation system, the PREFERENCE ELITE Pedicle Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar- first sacral (L5-S1) vertebral joint, (b) who are receiving fusions using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (d) who are having the device removed after the development of a solid fusion mass.

14. Technological Characteristics

    The Preference Elite Pedicle screw system is substantially equivalent to the predicate devices. The device was shown to be equivalent to the predicates in intended use/ indications for use, function, materials, sizes and sterilization.

15. Performance Data

    Testing and analyses were completed in accordance with the applicable standards.
    - ASTM F1717 Static Axial Compression Bending
    - ASTM F1717 Static Torsion
    - ASTM F1717 Dynamic Axial Compression Bending
    - ASTM F1798 Static Pull-off

    The testing results demonstrate that the new system, Preference Elite Pedicle Screw System, is substantially equivalent to the predicates.

16. Guidance Referenced

    - 2015 Food and Drug Administration, Guidance for Industry and FDA Staff –Processing/re-processing Medical Devices in Healthcare Settings
    - 2004 Food and Drug Administration, Guidance for Industry and FDA Staff- Spinal System 510(k)s.

17. Conclusions

The Preference Elite Pedicle Screw System is substantially equivalent to the predicate systems in regards to intended use, indications for use, design, materials, sizes and sterility. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence to the predicate systems.