April 6, 2018

Valorus Spine
% Mr. Nicholas M. Cordaro
CEO
Watershed Idea Foundry
1815 Aston Avenue, Suite 106
Carlsbad, California 92008

Re: K180324
Trade/Device Name: Patriot Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 2, 2018
Received: February 5, 2018

Dear Mr. Cordaro:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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)*

K180324

Device Name
Patriot Spinal Fixation System

Indications for Use *(Describe)*

The Patriot Spinal Fixation System, when used in the non-cervical posterior spine (T1 to S1), is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal stenosis, tumor, pseudoarthrosis, and failed previous fusion.

In addition, when used placed between L5 and S1, the Patriot Spinal Fixation System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) in skeletally mature patients receiving fusion with autologous bone graft.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(K180324)

DATE PREPARED
January 11, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Patriot Spinal Fixation System

COMMON NAME
Pedicle Screw Spinal System

DEVICE CLASSIFICATION
Thoracolumbosacral Pedicle Screw System
(Classification Regulations: 21 CFR 888.3070, Product Code: NKB, Class: II)

PREMARKET REVIEW
ODE/DOD/ Posterior Spine Devices Branch (PSDB)
Orthopedic Panel

INDICATIONS FOR USE
The Patriot Spinal Fixation System, when used in the non-cervical posterior spine (T1 to S1), is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal stenosis, tumor, pseudarthrosis, and failed previous fusion.

In addition, when used placed between L5 and S1, Patriot Spinal Fixation System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) in skeletally mature patients receiving fusion with autologous bone graft.

DEVICE DESCRIPTION

The Patriot Spinal Fixation System is a posterior, non-cervical, spinal fixation system consisting of a variety of shapes and sizes of rods, screws, and crosslinks, to provide temporary internal fixation and stabilization during bone graft healing as an adjunct to fusion of the thoracic, lumbar and sacral spine.

PREDICATE DEVICE IDENTIFICATION

The Patriot Spinal Fixation System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K955348	DePuy (Acromed), Titanium Moss Miami Spinal System,	
K161363	Alphatec Spine, Arsenal Spinal Fixation System	✓
K101278	Nexxt Spine LLC, Inertia Pedicle Screw System	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Patriot Spinal Fixation System. The following tests were performed to demonstrate safety based on current industry standards:

- Static and dynamic compression (per ASTM F1717)
- Static torsion (per ASTM F1717)

The results of these tests indication that the Patriot Spinal Fixation System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

The Valorus Patriot Spinal Fixation System is similar to the cited predicate device in regards to components, device description, intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical).

All implants are used to treat the same conditions, have essentially the same precautions and contraindications for use, and they represent a basic design concept in terms of safety and effectiveness, and differ only in design details and not functionality.

CONCLUSION

The Patriot Spinal Fixation System is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, including static and dynamic compression as well as static torsion (per ASTM F1717), it can be concluded that that the subject device is substantially equivalent when compared to the predicate devices.