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

Phamedica, Inc.
% Mr. Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

June 29, 2017

Re: K163011
Trade/Device Name: PHA S1 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: June 13, 2017
Received: June 14, 2017

Dear Mr. Maxwell:

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)*
K163011

Device Name

PHA S1 Spinal Fixation

Indications for Use *(Describe)*

Phamedica PHA S1 Spinal System is intended for posterior non-cervical pedicle fixation of Thoracic, Lumbar, Sacral/ Iliac Spine in skeletally mature patients, as an adjunct to fusion using autogeneous bone graft or allograft for all of the following indications:

- Degenerative Disc Disease (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
- Failed previous fusion in skeletally mature patients.

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.**

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

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# 5. 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Phamedica, Inc. |
| Submitter's Address: | 15 Newtown Rd<br>Plainview NY 11803 |
| Submitter's Telephone: | 719.291.6874 |
| Contact Person: | Kenneth C. Maxwell II<br>Empirical Consulting, LLC<br>719.337.7579 |
| Date Summary was Prepared: | 29 June 2017 |
| Trade or Proprietary Name: | PHA S1 Spinal Fixation |
| Common or Usual Name: | Orthosis, Spinal Pedicle Fixation<br>Orthosis, Spondylolisthesis Spinal Fixation<br>Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease |
| Classification: | Class II per 21 CFR §888.3070 Device Classification |
| Product Code: | NKB |
| Classification Panel: | Division of Orthopedic Devices |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Phamedica PHA S1 Spinal Fixation system consists of Poly Axial screws, Mono Axial Screws, Poly Axial and Mono Axial Reduction Screws, Rods, Set Screws, Transverse and Offset connectors made from Titanium Alloy Ti6AL4V which can be variously assembled for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.

## INDICATIONS FOR USE

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- Spinal Stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion in skeletally mature patients.

The indications for use for the PHA S1 Spinal System is similar to that of the predicate devices listed in Table 5-1.

Table 5-1 Predicate Devices

| **510k Number** | **Trade or Proprietary or Model Name** | **Manufacturer** | **Predicate Type** |
|---|---|---|---|
| K000236 | Synergy VLS Open | Interpore | Primary |
| | | | |
| K111940 | S 100 Pedicle Screw System | Renovis | Additional |

## PERFORMANCE DATA

The PHA S1 Spinal System has been tested in the following test modes:

- Static compression bending per ASTM F1717-15
- Static torsion per ASTM F1717-15
- Dynamic compression bending per ASTM F1717-15

The results of this non-clinical testing show that the strength of the PHA S1 Spinal System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the PHA S1 Spinal System is substantially equivalent to the predicate device.