DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2015

Precision Spine, Incorporated
Michael C. Dawson, Esq.
Director of Regulatory Affairs/Deputy General Counsel
2050 Executive Drive
Pearl, Mississippi 39208

Re: K151422
Trade/Device Name: Reform Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: August 5, 2015
Received: August 10, 2015

Dear Mr. Dawson:

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 yours,

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 on last page.

510(k) Number *(if known)*
K151422

Device Name
Reform Pedicle Screw System

Indications for Use *(Describe)*

The Reform Pedicle Screw System 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 of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Reform Pedicle Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation (T1-S1/ilium) for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; degenerative disc disease (DDD); pseudoarthrosis; and failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	973-455-7150 ext. 128
Contact Person:	Michael C. Dawson
Date Summary was Prepared:	May 26, 2015
Trade or Proprietary Name:	Reform Pedicle Screw System
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease Appliance, Fixation, Spinal Interlaminal
Classification:	Class III per 21 CFR §888.3070 and 888.3050
Product Code:	NKB, OSH, MNH, MNI, KWP
Classification Panel:	87 Orthopedic Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Reform System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, locking cap screws, hooks, domino connectors, and lateral offset connectors. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from medical grade stainless steel, cobalt chromium alloys, titanium or titanium alloy described by such standards as ASTM F138, ASTM F1537, ISO 5832-12, ASTM F136 or ISO 5832-3. The pedicle screws are included with or without hydroxyapatite (HA) coating.

CHANGE FROM PREDICATE:

The purpose of this submission is to add hydroxyapatite (HA) coated pedicle screws to the PSS System (Reform Pedicle Screw System) cleared in K143248, K131343, K130279, K121172, K092128, K090033, K073240, and K071438.

INDICATIONS FOR USE

The Reform Pedicle Screw System 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 of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (psuedoarthrosis).

The Reform Pedicle Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation (T1-S1/ilium) for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; degenerative disc disease (DDD); pseudoarthrosis; and failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the modifications/additions to the components of the PSS System (Reform Pedicle Screw System) do not substantially differ from the legally marketed predicate devices, which are the PSS System (Reform Pedicle Screw System, K143248, K131343, K130279, K121172, K092128, K090033, K073240, and K071438) and the Biomet Polaris Spinal System (K141804, K133746, K131615). The predicate devices and the subject addition to the PSS (Reform) system is designed for posterior stabilization to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

Reform Pedicle Screw System is manufactured from medical grade stainless steel, cobalt chromium alloys, titanium or titanium alloy described by such standards as ASTM F138, ASTM F1537, ISO 5832-12, ASTM F136 or ISO 5832-3. The pedicle screws are included with or without hydroxyapatite (HA) coating. The implants are provided sterile and non-sterile with instructions for sterilization. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sterilization

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Primary or Additional**
K143248, K131343, K130279, K121172, K092128, K090033, K073240, and K071438	PSS System (Reform Pedicle Screw System)	Precision Spine (Spinal USA)	Primary
K143248, K133746, K131615	Polaris Spinal System	Biomet Spine	Additional

PERFORMANCE DATA

Analysis was performed to show that the subject devices are substantially equivalent to the predicate devices and do not require additional mechanical testing. To support substantial equivalence, a clinical literature assessment was conducted using published clinical data for pedicle screw fixation. The assessment concluded that pedicle screw fixation is safe and effective for use in pediatric patients.

CONCLUSION

The overall technology characteristics and mechanical engineering analysis lead to the conclusion that the Reform Pedicle Screw System is substantially equivalent to the predicate device.