December 19, 2017

Precision Spine, Inc.
% Meredith L. May, MS, RAC
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K173130
Trade/Device Name: Reform® Midline Cortical Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 28, 2017
Received: September 29, 2017

Dear Ms. May:

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 on last page.

510(k) Number *(if known)*
K173130

Device Name
Reform® Midline Cortical Screw System

Indications for Use *(Describe)*

The Reform® Midline Cortical Screw System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for 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; and/or failed previous fusion.

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

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	973-455-7150
Contact Person:	Meredith L May MS RAC Empirical Consulting LLC 719-337-7579
Date Summary was Prepared:	October 27th, 2017
Trade or Proprietary Name:	Reform® Midline Cortical Screw System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The modular system titanium bone screws have a dual-lead cortical-cancellous thread form and are offered in both cannulated and non-cannulated versions with diameters ranging from Ø4.5 – 9.5mm. The cobalt chrome tulips are offered in both standard and reduction style. The cobalt-chrome rods are offered in multiple lengths with a Ø4.75mm. Various connectors are also provided with this system.

INDICATIONS FOR USE

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

TECHNOLOGICAL CHARACTERISTICS

Reform® Midline Cortical Screw System is made from materials that conform to ASTM standards. 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

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K150856	Reform Pedicle Screw System	Precision Spine	Primary
K171082	JANUS Midline	Orthofix	Additional

PERFORMANCE DATA

The Reform® Midline Cortical Screw System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717
- Static torsion per modified ASTM F1717
- Dynamic axial compression bending per ASTM F1717

Additionally, static tulip-shank dissociation testing was performed on the polyaxial screw per ASTM F1798.

The results of this non-clinical testing show that the strength of the Reform® Midline Cortical Screw 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 Reform® Midline Cortical Screw System is substantially equivalent to the predicate device.