May 19, 2020

Precision Spine
% Mr. J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K200303
Trade/Device Name: Reform Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: April 7, 2020
Received: May 14, 2020

Dear Mr. Webb:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200303

Device Name

Reform Pedicle Screw System

Indications for Use *(Describe)*

The Reform Pedicle Screw System is intended for 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 disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion. The Reform Pedicle Screw System is to be used with autograft and/or allograft.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Reform Pedicle Screw System is intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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."

PSC Publishing Se
443-6740 EF

510(k) Summary: Reform® Pedicle Screw System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	April 6, 2020
Submitted By	Precision Spine, Inc. 2050 Executive Drive Pearl, MS 39208
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 jdwebb@orthomedix.net
Secondary Contact	Michael C. Dawson Precision Spine 2050 Executive Drive Pearl, MS 39208 973-455-7150 ext. 128
Trade Name	Reform Pedicle Screw System
Common Name	Thoracolumbosacral Pedicle Screw System Appliance, Fixation, Spinal Interlaminal
Classification Name	Thoracolumbosacral Pedicle Screw System Spinal Interlaminal Fixation Orthosis
Class	II
Product Code	NKB KWP
CFR Section	21 CFR section 888.3070 and 888.3050
Device Panel	Orthopedic
Primary Predicate Device	Reform Polyaxial Pedicle Screw System - Precision Spine, Inc. (K150856)
Secondary Predicate Devices	Reform HA Coated Pedicle Screw System – Precision Spine, Inc. (K151422) Firebird Spinal Fixation System – Orthofix, Inc. (K122901)
Device Description	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. The pedicle screws are included with or without hydroxyapatite (HA) coating
Materials	Cobalt chromium alloys (ASTM F1537, ISO 5832-12) Titanium alloy (ASTM F136, ISO 5832-3) Hydroxyapatite (HA) (ASTM F1185)
Intended Use	The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System are 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.
Substantial Equivalence Claimed to Predicate Devices	The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The **Reform Pedicle Screw System** is intended for 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 disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion. The Reform Pedicle Screw System is to be used with autograft and/or allograft. When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the **Reform Pedicle Screw System** implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the **Reform Pedicle Screw System** is intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System and the predicate devices are all intended to be used for immobilization and stabilization of spinal segments. <u>Materials</u> The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System use the same material as the predicates. <u>Design</u> The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System and the predicates are equivalent in terms of shape and function. <u>Dimensions</u> The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System and the predicates are equivalent in their dimensions. <u>Strength</u> The Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System have greater or equivalent strength values compared to the predicates.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic axial compression bending - ASTM F1717 • Static torsion - ASTM F1717 • Integrity of Package Seals - ASTM F1886 • Package Seal Strength - ASTM F88 • Detecting Seal Leaks - ASTM F1929 • Testing of Shipping Containers - ASTM D4169 • Detecting Leaks in Medical Packaging - ASTM F2096 • Bacterial Endotoxins – Test Methods, routine monitoring, and alternatives to batch testing - AAMI ST72:2019 • Medical Devices – Bacterial Endotoxin and Pyrogen Test - USP <161> • Bacterial Endotoxin Test - USP <85> The results of these evaluations indicate that the Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System are equivalent to predicate devices.

Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Precision Spline considers the Reform Pedicle Screw System and Reform HA Coated Pedicle Screw System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and mechanical testing.