



December 17, 2024

Precision Spine, Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242297

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, PML
Dated: November 26, 2024
Received: November 26, 2024

Dear Nathan Wright:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S 

Colin O'Neill, M.B.E.

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

Indications for Use

Submission Number (if known)

K242297

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 disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; 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.

When used in conjunction with G21 V-Fast or V-Steady Bone Cement and PicoMix™ V and/or V-HP Gun with the G21 and Precision Spine Cement Cannula for mixing and injection of bone cements, the fenestrated Reform pedicle screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The fenestrated Reform pedicle screws augmented with G21 V-Fast or V-Steady Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

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K242297 - 510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, Mississippi 39208
Submitter's Telephone:	201-953-0500
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	August 1, 2024
Trade or Proprietary Name:	Reform Pedicle Screw System
Device Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification & Regulation #:	Class II per 21 CFR §888.3070, §888.3027
Product Code:	NKB, PML
Classification Panel:	Orthopedic – Spinal (DHT6B)



PURPOSE OF SUBMISSION:

The purpose of this submission is to offer fenestrated screws in the previously cleared Reform Pedicle Screw System for bone cement injection.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Reform Pedicle Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, locking cap screws, hooks, dominoes, and lateral offsets. All of the components are available in a variety of sizes to match more closely 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 products are supplied clean and "non-sterile". The Fenestrated Screws allow the augmentation of PMMA bone cement to the insertion site. These modular Fenestrated Screws are assembled during surgery with the Reform Standard Modular Tulips or the Reform Reduction Modular Tulips which were cleared under K150856 and their compatible rods and set screws. The Fenestrated Screws are to be used with the G21 V-Fast Bone Cement or V-Steady Bone Cement cleared under K150408. Bone Cement is delivered into the pedicle screw and bone through the delivery instrumentation.

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 disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

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TECHNOLOGICAL CHARACTERISTICS

Predicate Devices

510k #	Trade or Proprietary Name	Manufacturer	Product Code	Type
K200596	G21 Cement, Vader® Pedicle System	Icotec AG	PML, NKB	Primary
K193011	CD Horizon Fenestrated Screw Set	Medtronic Sofamor Danek USA, Inc.	NKB	Additional
K150856	Reform Pedicle Screw System	Precision Spine, Inc.	NKB, KWP, MNH, MNI, OSH	Additional

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. 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 same between the subject and predicates:

- Indications for Use
- Structural Support Mechanism and Function
- Materials of manufacture
- Sterility
- Sizes
- Manufacturing and Biocompatibility

Difference in fenestration diameters and differences in quantity of fenestrations at the screw tip do not raise questions for safety and efficacy since bone cement injection testing was performed with the subject fenestrated screws which demonstrated successful injection of bone cement through the fenestrations.

PERFORMANCE DATA

The Reform Pedicle Screw System has been tested in the following test modes:

- Dynamic Compression Bending per ASTM F1717
- Bone Cement Injection Testing

The results of this non-clinical testing show that the performance of the Reform Pedicle 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 Pedicle Screw System is substantially equivalent to the predicate device.