April 11, 2018

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

Re: K172495
Trade/Device Name: Reform® POCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 8, 2018
Received: March 15, 2018

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)*
K172495

Device Name
Reform® POCT System

Indications for Use *(Describe)*

The Precision Spine Reform® POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Precision Spine Reform® POCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of 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:	601.420.4244
Contact Person:	Meredith L. May, MS, RAC Empirical Consulting 719.291.6874
Date Summary was Prepared:	16 August 2017
Trade or Proprietary Name:	Reform® POCT System
Common or Usual Name:	Orthosis, Cervical Spinal Pedicle Fixation Appliance, Fixation, Spinal Interlaminal
Classification:	Unclassified
Product Code:	NKG, KWP

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Reform® POCT System is a posterior spinal fixation system intended for fusion of the Occipital, Cervical, and Thoracic regions of the spine (Occiput-T3). The system consists of a variety of rods, occipital plates, occipital screws, polyaxial screws, cross-connectors, lateral offset, domino connectors, and hooks to achieve an implant construct that closely matches patient anatomy. The Reform POCT System implants are fabricated from titanium, titanium alloy, or cobalt chromium alloys as described by standards such as ASTM F136, ASTM F1537, or ISO 5832-3. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together, however, should not be used with stainless steel. The system also includes the instruments necessary for inserting and securing the implants. The components are supplied clean and "NON-STERILE". All implants are single use only and should not be reused under any circumstances.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices are considered substantially equivalent as they are similar or identical in material, indications for use, sterility, and size offerings.

INDICATIONS FOR USE

The Precision Spine Reform® POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Precision Spine Reform® POCT System is also intended to restore the

integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The indications for use for the Reform® POCT 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**
K162300	Reform® POCT System	Precision Spine, Inc.	Primary
K151755	OASYS® System	Stryker	Additional
K153631	Virage®	Zimmer Spine	Additional

TECHNOLOGICAL CHARACTERISTICS

The following technological characteristics are similar between the subject and predicate devices:

- Indications for Use
- Principles of operation
- Materials
- Sterility

PERFORMANCE DATA

The Reform® POCT System has been tested in the following test modes:

- Dynamic axial compression per ASTM F2706
- Dynamic torsion per ASTM F2706

The results of this non-clinical testing show that the strength of the Reform® POCT System is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Reform® POCT System is substantially equivalent to the predicate device.