



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

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

June 4, 2015

Re: K150851

Trade/Device Name: Sure Lok Mini Posterior Cervical/Upper Thoracic System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: May 6, 2015  
Received: May 7, 2015

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.

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

**Indications for Use**

510(k) Number (if known)  
K150851

Device Name

Sure Lok Mini Posterior Cervical/Upper Thoracic System

Indications for Use (Describe)

When intended to promote fusion of the cervical spine (C1-C7) in skeletally mature patients, the Sure Lok Mini Posterior Cervical/Upper Thoracic System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiologic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for the purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical (C1-C7) spine.

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
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	973-455-7150
Contact Person:	Meredith May, MS, RAC Empirical Consulting, LLC 719.337.7579
Date Summary was Prepared:	27 March 2015
Trade or Proprietary Name:	Sure Lok Mini Posterior Cervical/Upper Thoracic System
Common or Usual Name:	Spinal interlaminar fixation orthosis
Classification:	Class II per 21 CFR §888.3050
Product Code:	KWP
Classification Panel:	Orthopedic Devices

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Sure Lok Mini Posterior Cervical/Upper Thoracic System consists of polyaxial screws, rods and Hooks. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from titanium alloy. The components will be provided non-sterile.

### INDICATIONS FOR USE

When intended to promote fusion of the cervical spine (C1-C7) in skeletally mature patients, the Sure Lok Mini Posterior Cervical/Upper Thoracic System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiologic studies)
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The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for the purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical (C1-C7) spine.

## TECHNICAL CHARACTERISTICS

The Sure Lok Mini Posterior Cervical/Upper Thoracic System is made from titanium alloy material that conforms to ASTM F136. The modification to the subject system, the addition of smooth shank screws, 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

### Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Type</b>
K112025	Sure Lok Mini Posterior Cervical/Upper Thoracic System	Precision Spine	Primary
K142741	OASYS®	Stryker Spine	Additional

## PERFORMANCE DATA

Risk analysis was conducted and led to the determination that additional mechanical testing is not required in order to establish the substantial equivalency of the subject devices to the predicate devices.

## CONCLUSION

The overall technology characteristics and mechanical engineering analysis lead to the conclusion that the Sure Lok Mini Posterior Cervical/Upper Thoracic System is substantially equivalent to the predicate devices.