July 13, 2018

Presidio Surgical
% Meredith Lee May, MS, RAC
Vice President
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K180655
Trade/Device Name: Viking Lumbar Polyaxial Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: April 17, 2018
Received: April 18, 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180655

Device Name
Viking Lumbar Polyaxial Screw System

Indications for Use *(Describe)*
When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the Presidio Surgical Viking 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: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

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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510(K) SUMMARY

Submitter's Name	Presidio Surgical
Submitter's Address	1451 Danville Blvd. Suite 204 Alamo, CA 94507
Submitter's Telephone	925.400.3010
Contact Person	Meredith Lee May, MS, RAC VP, Empirical Consulting MMay@EmpiricalConsulting.com 719-337-7579
Date Summary was Prepared	05 March 2018
Trade or Proprietary Name	Viking Lumbar Polyaxial Screw System
Common or Usual Name	Thoracolumbosacral pedicle screw system
Classification	Class II per 21 CFR §888.3070
Product Code	NKB
Classification Panel	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Presidio Surgical Viking Lumbar Polyaxial Screw System is a polyaxial pedicle screw system with straight or precontoured crosslink to provide optimal supporting structure for the spinal bodies. The pedicle screw system is a surgically implantable device which is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine. This premarket notification is to add a new crosslink design to the pedicle screw system that was previously cleared.

INDICATIONS FOR USE

When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the Presidio Surgical Viking 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: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

TECHNICAL CHARACTERISTICS

The Viking Lumbar Polyaxial Screw System is made from material that conforms to ASTM F136. 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 the same between the subject and predicate devices:

- Indications for use
- Principles of operation
- Implant materials of manufacture
- Sterilization

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate**
K120091	Pedicle Screw System	R&D Innovation	Primary
K120832	Fortex Pedicle Screw System	X-Spine	Additional
K111940	S 100 Pedicle Screw System	Renovis	Additional

PERFORMANCE TESTING SUMMARY

In support of this Traditional 510(k) Device Modification Premarket Notification, Presidio Surgical has conducted confirmatory mechanical testing to demonstrate that the modifications to the Viking Lumbar Polyaxial Screw System provide adequate and substantially equivalent mechanical strength for their intended use. The testing that was completed was dynamic compression bending per ASTM F1717.

CONCLUSION

The Viking Lumbar Polyaxial Screw System modified subject device is very similar to the previously cleared Viking Lumbar Polyaxial Screw System. The subject device Viking Lumbar Polyaxial Screw System has the same intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data lead to the conclusion that the Viking Lumbar Polyaxial Screw System is substantially equivalent to the predicate devices.