



December 3, 2020

Integrity Implants Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K203367

Trade/Device Name: LineSider™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: November 13, 2020
Received: November 16, 2020

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 (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.
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

510(k) Number (*if known*)
K203367

Device Name
LineSider™ Spinal System

Indications for Use (*Describe*)

LineSider™ Spinal System, with or without MIS instrumentation, is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, LineSider™ Spinal 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, LineSider™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis; fracture caused by tumor and/or trauma. LineSider™ Spinal 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.”

510(K) SUMMARY

Submitter's Name:	Integrity Implants Inc.
Submitter's Address:	354 Hiatt Drive Palm Beach Gardens, FL 33418
Submitter's Telephone:	561-529-3861
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	November 13, 2020
Trade or Proprietary Name:	LineSider™ Spinal System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070 and per 21 CFR §888.3050
Product Code:	NKB, KWP
Classification Panel:	Orthopedic and Rehabilitation Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The LineSider™ Spinal System is a thoracolumbosacral pedicle screw system containing metallic implants intended to provide immobilization and stabilization of spinal segments. The system consists of a variety of screws, hooks, rods, set screws, crosslink connectors, rod-to-rod connectors, iliac connectors, and associated instruments. Components are offered in various shapes and sizes to meet the requirements of the individual patient anatomy. The LineSider™ Spinal System subject to this 510(k) adds non-modular screws to the line offered under K190360.

The purpose of this submission is to expand the LineSider™ Spinal System to include non-modular screws to the line of previously cleared screws.

INDICATIONS FOR USE

LineSider™ Spinal System, with or without MIS instrumentation, is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, LineSider™ Spinal 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, LineSider™ Spinal System is intended to treat

pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis; fracture caused by tumor and/or trauma. LineSider™ Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The indications for use for the subject LineSider™ Spinal System are identical to the indications of the previously cleared LineSider™ Spinal System (K190360).

TECHNICAL CHARACTERISTICS

The LineSider™ Spinal System implants are made from Ti-6Al-4V ELI conforming to ASTM F136, commercially pure titanium conforming to ASTM F67, and Co28-Cr6-Mo conforming to ASTM F1537. The subject system expands the LineSider™ Spinal System screws to include non-modular screws. 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 identical between the subject and predicates:

- Indications for Use
- Technological Characteristics
- Materials of manufacture
- Sizes

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K190360	LineSider™ Pedicle Screw System	Integrity Implants Inc.	Primary
K171170	M.U.S.T. Pedicle Screw System	Medacta International SA	Additional

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, Integrity Implants has conducted confirmatory mechanical testing to demonstrate that the modifications to the LineSider™ Spinal 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 subject LineSider™ Spinal System is very similar to the previously cleared LineSider™ Spinal System and the additional predicate. The subject LineSider™ Spinal System has similar 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 LineSider™ Spinal System is substantially equivalent to the predicate devices.