August 7, 2023

Integrity Implants Inc.
Alexa Kamer
Regulatory Affairs Specialist
354 Hiatt Drive
Palm Beach Gardens, Florida 33418

Re: K231098
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: April 14, 2023
Received: April 18, 2023

Dear Alexa Kamer:

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 -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

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)*
K231098

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.

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510(k) SUMMARY

LineSider® Spinal System

April 14, 2023

I.	**Company:**	Integrity Implants Inc. 354 Hiatt Drive Palm Beach Gardens, FL 33418 Telephone: 561-529-3861
II.	**Contact:**	Alexa Kamer Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	LineSider® Spinal System
IV.	**Common Name:**	Thoracolumbosacral Pedicle Screw System
V.	**Classification Name:**	Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
	Class:	II
	Product Code:	NKB, KWP

VI. Product Description

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.

VII. 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.

VIII. Summary of Technological Characteristics

LineSider® Spinal System implants are manufactured from Ti-6Al-4V ELI per ASTM F136, Grade 2 CP Ti (commercially pure titanium) ASTM F67, and Co28-Cr6-Mo (cobalt chromium) per ASTM F1537. The implants are provided non-sterile and are intended to be steam sterilized by the user prior to use. The implants are intended to be used with allograft and/or autograft. LineSider® Spinal System implants may be implanted via a posterior surgical approach. The system is used with manual surgical instruments for delivery of the implant device.

LineSider® pedicle screws are currently available in a non-modular configuration, as well as a modular configuration that allows the screws to be assembled in situ. The pedicle screws incorporate a ball and socket poly-axial design to achieve the flexibility and range of motion suitable for meeting varying patient anatomical needs.

The screw tulip heads are available in standard height open and closed versions, as well as with removable extended threaded tabs or removable extended threaded tower heads for a percutaneous approach. The heads have multiple attachment features that allow instrumentation to rigidly affix to the head and assist in screw deployment or rod manipulation

Set screws are available for mating with open or closed head components. All set screws are fully tightened after positioning of components using a torque limiting handle and counter torque tube to ensure immobilization of the assembled construct.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

Substantial equivalence of the subject LineSider® Spinal System to the following legally marketed predicate devices is claimed:

Primary Predicate: LineSider Spinal System K190360 (SE 06/21/2019)

Additional Predicate: LineSider Spinal System K203367 (SE 12/03/2020)

X. Brief Discussion of the Non-Clinical and Clinical Tests Submitted

Integrity Implants has conducted bench performance testing in support of this premarket notification submission as follows:

- Static Compression Bending in accordance with ASTM F1717-21
- Static Torsion in accordance with ASTM F1717-21
- Dynamic Compression Bending in accordance with ASTM F1717-21
- Static Axial Grip in accordance with ASTM F1798-21
- Static Torsion Grip in accordance with ASTM F1798-21
- Static Flexion-Extension Bending in accordance with ASTM F1798-21
- Static Axial Pull-Off in accordance with ASTM F1798-21
- Static Axial Push-On in accordance with ASTM F1798-21

XI. Conclusions Drawn for the Non-Clinical and Clinical Tests

Based on the bench performance testing and other supporting documentation provided in this premarket notification, the subject LineSider® Spinal System demonstrates substantial equivalence to legally marketed predicate devices including the previously cleared LineSider Spinal System.