November 13, 2019

Grafton Medical Alliance
% Ms. Cassie Sopko
Regulatory Engineer
JALEX Medical
27865 Clemens Road, Suite 3
Westlake, Ohio 44145

Re: K192915
Trade/Device Name: GMA 2.0 Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: October 11, 2019
Received: October 15, 2019

Dear Ms. Sopko:

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,

Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K192915

Device Name
GMA 2.0 Pedicle Screw System

Indications for Use *(Describe)*
The GMA 2.0 Pedicle Screw System is intended for immobilization and stabilization of the spine. The GMA 2.0 Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous 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)

**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.***

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# 510(k) Summary

**Submitted By:** Grafton Medical Alliance
7416 S County Line Rd #E
Burr Ridge, IL 60527

**Date:** 10/11/19

**Contact Person:** Cassie Sopko
Contact Email: csopko@jalexmedical.com
**Contact Telephone:** (216) 307-3918
**Contact Fax:** (440) 933-7839

**Device Trade Name:** GMA 2.0 Pedicle Screw System
**Device Classification Name:** Thoracolumbosacral Pedicle Screw System
**Device Classification:** Class II
**Reviewing Panel:** Orthopedic
**Product Code:** NKB
**Primary Predicate Device:** K133063 SANTIS™ Pedicle Screw System
The predicate device has never been subject to a recall.

**Device Description:**

The GMA 2.0 Pedicle Screw System is comprised of pre-bent rods, pedicle screw assemblies with dual lead non-cannulated screws, and a set screw. Various forms and sizes of these implants are available to account for the unique anatomy of individual patients. Components are made of Ti6Al4V ELI conforming to ASTM F136. The system includes a set of instruments to aid in the implantation of the device. The instruments are made of medical grade stainless steel per ASTM F899.

**Description of Change:**

GMA purchased the predicate device (K133063) from Lanterna Medical Technologies. The purpose of this submission is for GMA to obtain clearance for additional instruments and a design change from the newly acquired, legally marketed predicate device.

Compared with the predicate device, the subject device has an updated instrument set, a modified screw design, and a modified pre-bent rod design. This submission includes the introduction of dual lead screws to reduce the insertion time for each implant. The number of threads per unit length is equivalent to the predicate. With this modification, each turn of the screw will result in further distance traveled, allowing for faster insertion.

The shape of the pre-bent rods was modified from a “hook” shaped end to a round, “cone” tipped end. The hook design is specifically used for minimally invasive surgery (MIS). Since this system is not designed for MIS, the rod design was modified. Additional sizes of the pre-bent rod were also introduced. Neither the screw, nor the rod design changes affect the the intended use of the implants. There were no changes to material or sterilization parameters. These changes and relevant risks are further discussed within the submission.

**Intended Use:**

The GMA 2.0 Pedicle Screw System is intended for immobilization and stabilization of the spine. The GMA 2.0 Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous fusion.

**Summary of Technological Characteristics:**

The GMA 2.0 Pedicle Screw System and the predicates have the same intended use and fundamental scientific technology. The table below compares the predicate to the subject device:

**Table 1: Comparison to Predicate**

| Information | Subject Device | Predicate | Equivalence |
|---|---|---|---|
| Common Name | Pedicle Screw System | Pedicle Screw System | Equivalent |
| Product Code | NKB | MNH, MNI, NKB | Equivalent |
| Materials | Titanium alloy | Titanium alloy | Equivalent |
| Intended Use | The GMA 2.0 Pedicle Screw System is intended for immobilization and stabilization of the spine. The GMA 2.0 Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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; | The Santis Pedicle Screw System is intended for immobilization and stabilization of the spine. The Santis Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous fusion. | Equivalent |

| | | | |
|---|---|---|---|
| | pseudoarthrosis; and failed previous fusion. | | |
| Description | Pre-bent rods, pedicle screw assemblies with dual lead non-cannulated screws, and a set screw | Straight and pre-curved rods, pedicle screw assemblies with both cannulated and non-cannulated screws, compression retaining assemblies, cross connectors and a set screw | Equivalent |

**Mechanical Testing:**

A full suite of mechanical testing was performed as part of the original submission (K133063). The introduction of the dual lead thread for the pedicle screws required additional testing to be performed to verify strength and safety. Axial pull out per ASTM F543, static torsion per ASTM F1717, and torque to failure per ASTM F543 testing was performed on the dual lead screws.

**Conclusion:**

Based on the indications for use, technological characteristics, mechanical testing, and overall comparison with the predicate device, the subject device has demonstrated substantial equivalence.