March 20, 2023

Integrity Spine
℅ Jennifer Palinchik
President
JALEX Medical
27865 Clemens Rd, Suite 3
Westlake, Ohio 44145

Re: K223043
Trade/Device Name: The Integrity Spine Core System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 22, 2023
Received: February 23, 2023

Dear Jennifer Palinchik:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223043

Device Name
The Integrity Spine Core System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the Integrity Spine Core System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

Submitted By: Integrity Spine
414 W Sunset Rd Ste 205
Dallas, TX 75206

Date: 03/16/2023

Contact Person: Jennifer Palinchik, President
JALEX Medical
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Integrity Spine Core System
Device Classification Name: Intervertebral Body Fusion Device with Bone Graft, Cervical
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: ODP
Predicate Device: K132718 Integrity Spine Core System
Additional Predicate: K133967 Aurora Spine Interbody Fusion System

The predicate devices have not been subject to any design related recalls.

Device Description:
The Integrity Spine Core System is a cervical interbody fusion system comprised of lordotic cages in two footprints with varying heights designed to accommodate patient anatomy and may be implanted as a single device via an anterior approach.

The Integrity Spine Core System implant components are made of polyether ether ketone (PEEK, Zeniva ZA-500) that conforms to ASTM F2026. The devices are plasma spray coated with titanium that conforms to ASTM F1580. Additionally, the devices contain tantalum markers that conform to ASTM F560 to assist the surgeon with proper placement of the device.

The Integrity Spine Core System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel that conforms to ASTM F899.

Intended Use:
When used as a cervical intervertebral body fusion device, the Integrity Spine Core System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Summary of Technological Characteristics:

The Integrity Spine Core System and the primary predicate have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Table 1. Technological Characteristics Comparison

Feature	Integrity Spine Core System (Subject)	Integrity Spine Core System (K132718)	Aurora Spine Interbody Fusion System (K133967)	Comparison
Classification Name	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Intervertebral Body Fusion Device with Integrated Fixation, Cervical	Equivalent
Regulation	888.3080	888.3080	888.3080	Equivalent
Product Code	ODP	ODP	ODP	Equivalent
Device Description	The Integrity Spine Core System is a cervical interbody fusion system comprised of lordotic cages in two footprints with varying heights designed to accommodate patient anatomy and may be implanted as a single device via an anterior approach. The Integrity Spine Core System implant components are made of polyether ether ketone (PEEK, Zeniva ZA-500) that conforms to ASTM F2026. The devices are plasma spray	The Integrity Spine Core System is a cervical interbody fusion system comprised of parallel and lordotic cages in two footprints with varying heights designed to accommodate patient anatomy and may be implanted as a single device via an anterior approach. The Integrity Spine Core System implant components are made of polyether ether ketone (PEEK, Zeniva ZA-500) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers that conform to ASTM F560 to assist the	The Aurora Spine Interbody Fusion System, manufactured from PEEK-Optima®, consist of implants available in various foot prints, heights, and lordotic configurations with an open architecture to accept packing of autograft materials. The exterior of the device has “teeth” or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned. The device comes in a PEEK or PEEK with a plasma-sprayed	Equivalent

Feature	Integrity Spine Core System (Subject)	Integrity Spine Core System (K132718)	Aurora Spine Interbody Fusion System (K133967)	Comparison
	coated with titanium that conforms to ASTM F1580. Additionally, the devices contain tantalum markers that conform to ASTM F560 to assist the surgeon with proper placement of the device. The Integrity Spine Core System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel that conforms to ASTM F899.	surgeon with proper placement of the device. The Integrity Spine Core System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel that conforms to ASTM F899.	commercially pure titanium coating on the superior and inferior surfaces.	
Intended Use	When used as a cervical intervertebral body fusion device, the Integrity Spine Core System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as	When used as a cervical intervertebral body fusion device, the Integrity Spine Core System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and	The Aurora Spine Interbody Fusion System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-	Equivalent

Feature	Integrity Spine Core System (Subject)	Integrity Spine Core System (K132718)	Aurora Spine Interbody Fusion System (K133967)	Comparison
	discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.	radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.	operative treatment prior to surgery. Cervical implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, supplemental fixation must be used.	
Interbody Heights	5-11 mm	5-11 mm	5-12 mm	Equivalent
Interbody Footprints	14x11 mm, 17x13 mm	14x11 mm, 17x13 mm	14x12 mm, 16x14 mm	Equivalent
Lordosis	6°	0° and 6°	5°	Equivalent
Implant Materials	PEEK Zeniva ZA-500 Per ASTM F2026, Titanium coating Per ASTM F1580, Tantalum markers Per ASTM F560	PEEK Zeniva ZA-500 Per ASTM F2026, Tantalum markers Per ASTM F560	PEEK Optima Per ASTM F2026, Titanium coating per ASTM F67, Tantalum markers Per ASTM F560	Equivalent

Non-clinical Testing:

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-11
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-11
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

Conclusion:

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