



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Integrity Spine  
% Ms. Lisa Peterson  
Principal Consultant  
Kaedon Consulting, LLC  
14001 Hunters Pass  
Austin, Texas 78734

November 10, 2015

Re: K151819

Trade/Device Name: Integrity Spine Lumbar Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: October 12, 2015  
Received: October 15, 2015

Dear Ms. Peterson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151819

Device Name  
Integrity Spine Lumbar Interbody Fusion System

### Indications for Use (Describe)

The Integrity Spine Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The device system is designed for use with supplemental fixation and with autograft to facilitate 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.

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**510(k) Summary**  
**Integrity Spine Lumbar Interbody Fusion System**  
**Premarket Notification**

<b>SUBMITTED BY</b>	Integrity Spine 2800 NE Loop 410 Suite 203 San Antonio, TX 78218
<b>ESTABLISHMENT REGISTRATION NUMBER</b>	3010763958
<b>OWNER/OPERATOR NUMBER</b>	10046086
<b>CONTACT PERSON</b>	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746 Fax: 512-266-3364 <a href="mailto:lpeterson@kaedonconsulting.com">lpeterson@kaedonconsulting.com</a>
<b>DATE PREPARED</b>	October 12, 2015
<b>CLASSIFICATION NAME</b>	Intervertebral Body Fusion Device
<b>DEVICE CLASS</b>	Class II
<b>REGULATION NUMBER</b>	21 CFR 888.3080 (Product Code MAX)
<b>COMMON NAME</b>	Intervertebral Fusion Device with Bone Graft, Lumbar
<b>PROPRIETARY NAME</b>	Integrity Spine Lumbar Interbody Fusion System

## IDENTIFICATION OF PREDICATE DEVICE(S)

Predicate devices include various cleared interbody fusion systems:

### Primary

- DiFusion: Xiphos Interbody Fusion System (K100042)

### Secondary

#### Additional Predicate

- DePuy Acromed: Lumbar I/F Cage (P960025)

#### Reference Devices

- Eminent Spine: Eminent Spine Interbody Fusion System (K090064)
- Medtronic: InterFix System (P970015)
- SeaSpine: SeaSpine Spacer System (K082310)
- Tyber Medical: Tyber Medical Interbody System (K130573)
- Spinal USA: Spinal USA Interbody Fusion Device (K092193)

## DEVICE DESCRIPTION

The Integrity Spine Lumbar Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy. The Integrity Spine lumbar interbody fusion device(s) may be implanted:

- bi-laterally in pairs via a posterior (PLIF) approach;
- as a single device via an oblique (OLIF) approach;
- as a single device via a transforaminal (TLIF) approach; or
- as as a single device via an anterior or anterolateral (ALIF) approach.

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

## INDICATIONS

The Integrity Spine Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

### **SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The purpose of this premarket notification is to obtain clearance to market the Integrity Spine Lumbar Interbody Fusion System. The Integrity Spine System is comprised of various device configurations based on surgical approach and patient anatomy. The implant components are made of polyether ether ketone (PEEK Zeniva ZA-500) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The subject system has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion:

- Intended for use at either one level or two contiguous levels, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-11 ), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

### **DISCUSSION OF 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

### **CONCLUSIONS**

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Integrity Spine Lumbar Interbody Fusion System is substantially equivalent to the predicate device.