



Food and Drug Administration
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Corentec Company, Limited
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REPUBLIC OF KOREA

October 2, 2015

Re: K151408
Trade/Device Name: LOSPA IS Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: September 1, 2015
Received: September 2, 2015

Dear Mr. Daniel:

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" (21 CFR 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)
K151408

K151408

Page 1 of 1

Device Name
LOSPA IS Spinal System

Indications for Use (Describe)

LOSPA IS PLIF&ALIF Cages are indicated for use with autogenous bone graft as intervertebral body fusion devices at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Patients should be skeletally mature and have had six months of non-operative treatment.

Devices are intended to be implanted via an open, posterior or anterior approach and used with autogenous bone and supplemental fixation.

LOSPA IS ACIF Cage is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine.

Patients should have received at least six weeks of non-operative treatment prior to treatment with the device.

Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation.

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
Corentec Co., Ltd.
LOSPA IS Spinal System
31st Aug 2015

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: LOSPA IS Spinal System
Common Name: Intervertebral body fusion device
Classification Regulations: 21 CFR 888.3080
Regulatory Class: II
Product Codes: MAX, ODP
Classification Panel: Orthopedic Products Panel
Reviewing Branch: Orthopedic Devices Branch

INDICATIONS FOR USELOSPA IS PLIF&ALIF Cage

LOSPA IS PLIF&ALIF Cages are indicated for use with autogenous bone graft as intervertebral body fusion devices at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Patients should be skeletally mature and have had six months of non-operative treatment. Devices are intended to be implanted via an open, posterior or anterior approach and used with autogenous bone and supplemental fixation.

LOSPA IS ACIF Cage

LOSPA IS ACIF Cage is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine.

Patients should have received at least six weeks of non-operative treatment prior to treatment with the device.

Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation.

DEVICE DESCRIPTION

The LOSPA IS Spinal Systems consisting of PLIF, ALIF & ACIF Interbody Fusion Devices is available in various heights and Lordotic configurations with an open architecture to accept packing of bone graft material. The design features are common with the design features of all the predicate devices as described below,

- Straight and wedge / Lordotic designs to match vertebral anatomy
- Adequate interior graft space for optimal bony integration
- Superior and inferior ridges designed to prevent implant migration
- Similar structural characteristics, open architecture to accept packing of autograft
- PEEK Cages (ASTM F2026) with radio-dense markers (Tantalum – ASTM F 560) for optimum fluoroscopic placement and post operative examination
- Available in multitude of similar sizes and lordotic

LOSPA IS PLIF Cage

- Three versions are available according to the lordotic angles (0°, 4°, 8°)
- It has various heights (8~16 mm) and lengths (22, 25, 28, 31, 34 mm)

LOSPA IS ALIF Cage

- Four versions are available according to the lordotic angles (6°, 8°, 12°, 15°)
- It has various heights (8~16 mm) and lengths (22, 25, 28, 31, 34 mm)

LOSPA IS ACIF Cage

- Available in a convex version with 5° lordotic angle.
- It has various heights (5~12 mm), widths (12, 14 mm) and depths (14, 16 mm)

LOSPA IS SPINAL SYSTEM INSTRUMENTATION

The LOSPA IS Spinal Systems consisting of PLIF, ALIF & ACIF Interbody Fusion Devices instrumentation consists of set of accessories to be used with LOSPA Cage implants. The instrumentation is classified as Class I & Class II. Class II instrumentations

includes implant specific instrumentations. The instruments are designed similar to devices already in market and is simple, conventional, and accurate. The parts of the instruments are made of stainless steel and polymers which are biocompatible and used in medical industry for decades. The instrumentation is used for their respective procedures by qualified orthopedic surgeons.

SUBSTANTIAL EQUIVALENCE

The LOSPA IS Spinal System is similar to the 510(k) cleared devices as mentioned below with respect to indications, design, operating principles and material.

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K073470	AVS PL Peek Spacer (O.I.C)	Stryker	Primary
K103111	FORZA Spacer	Orthofix Inc.	Additional
K122639	SynCage Evolution	DepuySynthes	Additional
K042714	Fidji	Zimmer	Additional
K120275	ACIS	DePuySynthes	Additional
K083311	CeSpace	Aesculap	Additional

The LOSPA IS PLIF Cages have a tapered leading edge similar to the primary predicate device AVS PL Peek Spacer (O.I.C) [K073470] and additional predicate device, FORZA Spacer System [K103111], with central canal to receive bone graft and has either straight/wedged shaped designs or Lordotic designs to match the vertebral anatomy. The overall design and dimensional specification of LOSPA IS PLIF Cages is similar to its predicate devices.

The LOSPA IS ALIF Cages has a profile similar to additional predicate devices such as the SynCage Evolution [K122639] and Fidji [K042714], with central canal to receive bone graft and has either straight/wedged shaped designs or Lordotic designs to match the vertebral anatomy. The overall design and dimensional specification of LOSPA IS ALIF Cages is similar to its predicate devices.

The LOSPA IS ACIF Cages has a profile similar to additional predicate devices such as the ACIS [K120275] and CeSpace [K083311], with central canal to receive bone graft and has convex configuration with lordotic angle. The overall design and dimensional specification of LOSPA IS ACIF Cages is similar to its additional predicate devices.

The design features of LOSPA IS Spinal Systems consisting of PLIF, ALIF & ACIF Interbody Fusion Devices are common with of all the predicate devices as described in device description.

At a high level, the LOSPA IS PLIF & ALIF and LOSPA IS ACIF Interbody Fusion Devices have the following similarities to the predicate devices:

- has the same intended use,
- has same indications for use,
- uses the same operating principles,
- incorporates the same basic designs & specifications,
- incorporates the same or similar materials, and
- is supplied Non Sterile and/or Sterile

PERFORMANCE DATA

Performance testing was carried out to demonstrate substantial equivalence and included methods described in the following standards: ASTM F 2077 and ASTM F 2267. Mechanical testing of the subject device consisted of static axial compression, static compression shear, static torsion, dynamic axial compression, dynamic compression shear, dynamic torsion, subsidence and expulsion testing. The static and dynamic testing's, subsidence and expulsion results demonstrated that the subject device performed either similar or better than comparable predicate devices, there by establishing substantial equivalence for performance. Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.

STERILIZATION & PACKAGING

Similar to the predicate devices, the LOSPA IS Spinal Systems consisting of PLIF, ALIF & ACIF Interbody Fusion Devices are packaged in pouch and supplied sterile and non-sterile.

The non-sterile implants and all instruments used in the surgery must be sterilized by the end user, prior to use, as mentioned in the IFU. *Steam sterilization validation for the subject non sterile devices was conducted as per, ISO 17665-1.*

For the sterile components, following to gamma sterilization, packaging was subjected to sterile barrier testing to validate a shelf life of 5 years as per ISO & ASTM standards

confirms the stability and effectiveness of packaging of the sterilized product during the shelf-life, by evaluating changes by accelerated aging, as per ASTM F1980.

Gamma sterilization validation for the subject sterile devices was conducted as per, ISO 11137-1 & ISO 11137-2.

CONCLUSION

Overall, the LOSPA IS PLIF & ALIF Cages & LOSPA IS ACIF Cages are similar to the identified primary predicate device and additional predicates. Any differences in technological characteristic between the subject and primary predicate device and additional predicate do not raise new issues of safety or efficacy and has been adequately addressed in this premarket notification.