DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 31, 2017

Corentec Co., Ltd
J.S. Daniel
Associate Director - Global RA&QA
8F Chungho Tower, 483, Gangnam-daero
Seocho Gu, Seoul, 06541 Korea

Re: K170243
Trade/Device Name: LOSPA IS TLIF & DLIF Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 23, 2017
Received: March 24, 2017

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170243

Device Name

LOSPA IS TLIF & DLIF Cages

Indications for Use *(Describe)*

LOSPA IS PLIF/T-PLIF & ALIF & TLIF & DLIF Cages are indicated for use with autogenous bone graft as an intervertebral body fusion device 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.

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 TLIF & DLIF Cages

20th March, 2017

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA IS TLIF & DLIF Cages
Common Name:	Inter body Fusion Cage
Classification Regulations:	21 CFR 888.3080
Regulatory Class:	2
Product Codes:	MAX
Regulation Medical Specialty:	Orthopedic
Reviewing Panel:	Orthopedic

INDICATIONS FOR USE

LOSPA IS PLIF/T-PLIF & ALIF & TLIF & DLIF Cage is indicated for use with autogenous bone graft as an intervertebral body fusion device 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.

DEVICE DESCRIPTION

LOSPA IS TLIF & DLIF Interbody fusion devices are 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 the predicate devices, Straight and wedge / Lordotic designs to match vertebral anatomy, Large interior graft space for optimal bony integration, Superior and inferior ridges designed to prevent implant migration, PEEK Cages with Tantalum markers for optimum fluoroscopic placement and post operative examination, Available in multitude of similar sizes to suit the individual pathology and anatomic condition of the patient. It is made of PEEK (ASTM F2026) & Tantalum (ASTM F560).

LOSPA IS TLIF Cage is available in

- Two versions are available according to the lordotic angles (0° & 7°).
- It has various heights (8~16 mm) and lengths (24, 29, 32, 35 mm).
- Two shapes, LOSPA IS TLIF Cage & LOSPA IS TLIF Cage B type.

LOSPA IS DLIF Cage is available in

- Four versions are available according to the lordotic angles (0°, 6°, 12° & 18°).
- It has various heights (8~16 mm), widths (18 & 22 mm) and lengths (40, 45, 50, 55, 60 mm).

<u>LOSPA IS SPINAL SYSTEM INSTRUMENTATION</u>

LOSPA IS Spinal Fixation System Instrumentation which includes instruments for subject devices LOSPA IS TLIF & DLIF Cages consisting of set of accessories to be used with LOSPA IS TLIF & DLIF Cages. The instruments are designed to be simple, conventional, and accurate and all parts of which are used for their respective procedures by qualified orthopedic surgeons. The parts of the instruments are made of stainless steel and polymers which are biocompatible and have been used in the medical industry for over a decade. All the materials used are cleared for use in PMN.

SUBSTANTIAL EQUIVALENCE

The LOSPA IS TLIF & DLIF Cages are similar to the 510(k) cleared devices as mentioned below with respect to indications, design, operating principles and material.

Subject Devices	Predicate Category	Manufacturer	Trade Name	510(k)
LOSPA IS Spinal Systems **TLIF Cages**	**Primary**	**Corentec Co. Ltd.**	**LOSPA IS Spinal Systems (PLIF/ALIF/ACIF)**	**K151408**
	Additional	Biomet Spine (Zimmer)	Zyston Curve Interbody Spacer	K110650
		K7 LLC	K7 Lumbar Spacers	K133126
LOSPA IS Spinal Systems **DLIF Cages**	**Primary**	**Corentec Co. Ltd.**	**LOSPA IS Spinal Systems (PLIF/ALIF/ACIF)**	**K151408**
	Additional	Medtronic	CLYDESDALE Spinal System	K100175
		DePuy Synthes	ORACLE Cage System	K072791

The LOSPA IS Spinal Systems consisting of TLIF & DLIF Interbody fusion devices and all the predicate devices have same intended use and similar indications for use.

The LOSPA IS TLIF Cages has a kidney bean shape similar with predicate Zyston Curve Interbody Spacer [K110650] and K7 Lumbar Spacers [K133126], with central canal to receive bone graft and has either straight shaped designs or wedge/Lordotic designs to match the vertebral anatomy. The overall design and dimensional specification of LOSPA IS TLIF Cages is similar to its predicate devices.

The LOSPA IS DLIF Cage has a convex & bullet nosed shaped interbody fusion device similar with predicate CLYDESDALE Spinal System [K100175] and ORACLE Cage System [K072791], with central canal to receive bone graft and has either straight shaped designs or wedge/Lordotic designs to match the vertebral anatomy. The overall design and dimensional specification of LOSPA IS DLIF Cages is similar to its predicate devices.

The design features of the LOSPA IS Spinal Systems consisting of LOSPA IS TLIF & DLIF Cages are common with of all the predicate devices as described in the device description.

At a high level, the LOSPA IS Spinal Systems consisting of TLIF & DLIF Interbody fusion devices has the following similarities to the predicate devices:

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

PERFORMANCE DATA

LOSPA IS TLIF & DLIF Cages, performance testing was carried out to demonstrate substantial equivalence and included methods described in the standard ASTM F2077 & AAMI ST72. Testing of the subject devices consisted of static axial compression, static compression shear and Pyrogen Testing.

The static results demonstrated that the subject devices are expected to be as safe and as effective as the predicate devices. 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 TLIF & DLIF Cages 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 TLIF & DLIF 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.