March 6, 2020

Corentec Co., Ltd.
Sungwon Yang
Director- QA&RA
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk-Gu
Cheonan-si, 31056 Kr

Re: K200267
Trade/Device Name: LOSPA® IS™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: December 6, 2019
Received: February 3, 2020

Dear Sungwon Yang:

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,

for

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)*

K200267

Device Name

LOSPA® IS™ Spinal Fixation System

Indications for Use *(Describe)*

The LOSPA IS Spinal Fixation Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). When used as an anterior screw fixation system, The LOSPA Spinal Fixation Systems are indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, Spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

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 Fixation System
LOSPA® IS™ Thoracolumbar Pedicle Screw
Rhino™ Percutaneous Pedicle Screw
6th Dec.,2019

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA® IS™ Spinal Fixation System
Common Name:	Thoracolumbosacral Pedicle Screw System
Classification Regulations:	21 CFR 888.3070
Regulatory Class:	Class II
Product Codes:	NKB, KWQ
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INDICATIONS FOR USE

The LOSPA IS Spinal Fixation Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). When used as an anterior screw fixation system, The LOSPA IS Spinal Fixation Systems are indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

DEVICE DESCRIPTION

The LOSPA IS Spinal Fixation System is a temporary, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screw fixation to the non-cervical spine. The LOSPA® IS™ Spinal Fixation System consists of an assortment of pedicle screws, set screws, lateral offsets, bone screws and screw bodies. The LOSPA® IS™ Spinal Fixation System implants are not compatible with components or metal from any other manufacturer's system.

The LOSPA IS Spinal Fixation System is this submission comprises of the following components,

A. Pedicle Screws (Mono-axial & Poly-axial), standard, guided, cannulated, cannulated MIS types, with screw diameters from 4.0 mm to 8.5mm (to 9.5 mm only Poly-axial) and length range from 20 mm to 140 mm, made up of Titanium Alloy (ASTM F 136).

B. Straight Rods of diameter of 5.5 mm and 6.0 mm (Standard) made up of Titanium Alloy (ASTM F 136).

C. Prebent Rods of diameter 5.5mm (Standard & Bullet types) and 6.0 mm(Standard, Bullet, MIS) made up of Titanium Alloy (ASTM F 136) & CoCr (ASTM F 1537)

D. Rod link made up of Titanium Alloy (ASTM F 136).

All the components are manufactured from medical grade titanium alloy (ASTM F 136) & CoCrMo alloy (ASTM F 1537).

SUBSTANTIAL EQUIVALENCE

LOSPA IS Spinal Fixation System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Substantially equivalent products for LOSPA IS Spinal Fixation System are as follows,

Device Type	**Manufacturer**	**Trade or Proprietary or Model Name**	**510(k)**	**Reference for**
Primary Predicate	Corentec Co., Ltd.	LOSPA IS Spinal System	K132644	All components
	Corentec Co., Ltd.	AEGIS & AEGIS II Spinal Systems (Renamed as LOSPA IS Spinal System)	K092076	
Additional	Stryker	Xia 3 Spinal System	K071373(T),	Pedicle

Predicate			K083393(T), K091291(S)	Screws
	L&K BIOMED	LnK Spinal Fixation system	K143363	
	SpineVision, S.A.	SpineVision LUMIS™ Cannulated Pedicle Screw Fixation System, SpineVision U.L.I.S.™ Pedicle Screw Fixation System	K160124	Cannulated Screws
	MEDYSSEY CO., LTD.	ZENIUS SPINAL SYSTEM	K110283	
	DePuy Synthes	EXPEDIUM VERSE SPINE SYSTEM	K142185	MIS screws
	L&K Biomed Co., Ltd.	PathLoc-L MIS Spinal System	K183117 (K161766)	

The LOSPA IS Spinal Fixation System is similar to the cleared devices as mentioned above with respect to indications, design, operating principles and material. This system consists of various Pedicle screws (Mono-axial/ Poly-axial) with a variety of type designs such as standard, guided, cannulated (Poly-axial only), cannulated MIS (Short, Long) type. Rods (Straight, Standard, Bullet type) and Rod Link (A/B/C type) with a set screw, the assembly of which is intended to provide temporary stabilization following surgery to fuse the spine. The components of Pedicle screw (Mono-axial/ Poly-axial) and Set screw, Rod Link are available in titanium alloy (ASTM F136) specifications as non sterile. The rod components are available in titanium alloy (ASTM F136) or cobalt-chrome alloy (ASTM F1537) specifications as non sterile and are either straight or pre-bent in configuration.

Furthermore, the materials are included in this submission for all of components of the LOSPA IS Spinal system same as material cleared in Corentec's own reference devices.

The LOSPA IS Spinal Fixation System and the predicate devices components are similar in overall shape and design & materials used. The subject device and the predicate devices encompass a similar range of physical dimensions, including the diameter and length of pedicle screws II, Cannulated screws, MIS screws, and rods.
Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

PERFORMANCE DATA

Performance testing –mechanical testing was carried out to demonstrate substantial equivalence and the subject device performed either similar or better than comparable predicate devices.

The LOSPA IS Spinal Fixation System components were subjected to a series testing requirements to demonstrate substantial equivalence and included methods described in the following standards: ASTM F1717 (static and dynamic compression bending, static torsion); ASTM F543 (axial screw pull-out). Mechanical testing of the subject device

consisted of Rods & Pedicle screws compression bending test, Rods & Cannulated pedicle screws compression, Rod & Pedicle screws torsional test, dynamic fatigue test, pedicle screw axial pull-out test.

Overall, the LOSPA IS Spinal Fixation System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same materials, and
- has same packaging materials and processes.

STERILIZATION & PACKAGING

The LOSPA IS Spinal Fixation System is supplied non-sterile and cited predicate devices are non-sterile.

CONCLUSION

Corentec Co., Ltd. believes that the subject device is substantially equivalent to the legally marketed predicate device based on intended use, technology, materials, as well as the mechanical testing and biocompatibility assessment.