DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 5, 2017

Corentec Co., Ltd
J.S. Daniel
Senior Manager/Engineer – RA & QA
8f Chungho Tower, 483, Gangnam-daero
Seocho Gu
Seoul, South Korea 06541

Re: K161641
Trade/Device Name: LOSPA IS ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 11, 2016
Received: November 15, 2016

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,

Lori A. Wiggins -S

for
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)*
K161641

Device Name

LOSPA IS ACP System

Indications for Use *(Describe)*

LOSPA IS ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with following indication:

1) Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2) Trauma (including fractures)
3) Tumors
4) Deformities or curvatures (including kyphosis, lordosis or scoliosis)
5) Pseudoarthrosis
6) Failed previous 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Corentec Co., Ltd.

LOSPA IS ACP System

5th Jan., 2017

ADMINISTRATIVE INFORMATION

Manufacturer

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA IS ACP System
Common Name:	Intervertebral body fixation orthosis
Classification Regulations:	21 CFR 888.3060
Regulatory Class:	Class II
Product Codes:	KWQ
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Anterior Spine Devices Branch

INDICATIONS FOR USE

LOSPA IS ACP System

LOSPA IS ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with following indication:

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2) Trauma (including fractures)
3) Tumors
4) Deformities or curvatures (including kyphosis, lordosis or scoliosis)
5) Pseudoarthrosis
6) Failed previous fusion.

DEVICE DESCRIPTION

LOSPA IS ACP System

LOSPA IS ACP System is composed of a bone plate (a locking mechanism is preassembled to plates) and screws. The design features are common with the design features of the predicate devices. Plates have a Low profile with windows. A locking system between plate and screw which also prevents back out. Plates attach to the anterior cervical spine with a minimum of four screws per plate. The plate ranges in length to accommodate one, two, three, and four level procedures. Available in multitude of similar sizes to suit the individual pathology and anatomic condition of the patient. Screws are available as Self-tapping & Self-drilling types. Fixation can be Fixed, Variable or Hybrid types. Both the plate and screws are made of Titanium alloy as described in ASTM F136, ISO 5832-3. Implant is available as non-sterile & sterile.

LOSPA IS ACP System is available in

- Width of 18 mm & Thickness of 1.9 and 2.3 mm and Levels 1 to 4 with height ranging from 20 to 110 mm.
- Screw has Core Dia. 2.5 & Outer Dia. 4.0, 4.5 with length ranging from 12 to 18mm.

LOSPA IS SPINAL SYSTEM INSTRUMENTATION

LOSPA IS Spinal Fixation System Instrumentation which includes instruments for subject devices ACP System consisting of set of accessories to be used with LOSPA IS ACP System. 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 used in medical industry.

SUBSTANTIAL EQUIVALENCE

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

LOSPA IS Spinal Systems	Predicate Category	Manufacturer	Trade Name	510(k)
ACP System	**Primary**	Medtronic Sofamor Danek USA	ATLANTIS ACP System	K063100
	Additional	Howmedica Osteonics Corp. (Stryker)	REFLEX ACP System	K010115

The LOSPA IS Spinal Systems consisting of Anterior Cervical Plate System components and all the predicate devices have same intended use and same indications for use.
The LOSPA IS ACP System has a profile similar with primary predicate ATLANTIS ACP System [K063100] and additional predicate, REFLEX ACP System [K010115], with windows for graft. The overall design and dimensional specification of LOSPA IS ACP System is similar to its predicate devices.

The design features of LOSPA IS Spinal Systems consisting LOSPA IS ACP System are common with of all the predicate devices as described in device description. At a high level LOSPA IS ACP System Devices have the following similarities to the predicate devices:

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

PERFORMANCE DATA

For LOSPA IS ACP System performance testing was carried out to demonstrate substantial equivalence. Testing of the subject devices consisted of static compression & tension bending, static torsion, dynamic compression, axial pullout/pushout and torque to failure and Pyrogen testing and included methods described in the standard ASTM F1717 & ASTM F543 & AAMI ST72.

The results of this testing showed 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 ACP System 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.
Additionally, for sterile components, Pyrogen testing as per AAMI ST72 was conducted.

CONCLUSION

Overall, the LOSPA IS ACP System is 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.