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

April 3, 2015

L&K Biomed Co., Ltd.
Ms. Yerim An
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si
Geyonggi-do, 446-916
Korea

Re: K143360
Trade/Device Name: LnK Cervical Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 19, 2015
Received: March 23, 2015

Dear Ms. An:

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 Statement

510(k) Number (if known): K143360
Device Name: LnK Cervical Interbody Fusion Cage System

Indications For Use:

LnK Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LnK Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use	√	AND/OR	Over-The-Counter Use	
(Part 21 CER801 Subpart D)			(21 CER801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (OED)

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92:

1. Submitter:

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Contact Person: Yerim An

Date prepared: March 19, 2015

2. Device Identification

Trade Name	LnK Cervical Interbody Fusion Cage System
Common Name	Intervertebral Body Fusion Device
Product Code	ODP
Classification	Class II
Classification Name	Intervertebral body fusion device 21 CFR 888.3080

3. Predicate or legally marketed devices which are substantially equivalent

- **L&K BIOMED Co., Ltd**: LnK Cervical Interbody Fusion Cage System(K120840)

4. Description of the Device

LnK Cervical Interbody Fusion Cage System intended for use as an interbody fusion cage device and must be used with supplemental fixation. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The devices are made of PEEK-OPTIMA® LTl with marker pins made of Unalloyed Tantalum.

5. Intended use

LnK Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in

the cervical spine at the C3 to C7 disc levels using autograft bone. LnK Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

No	Item	LnK Cervical Interbody Fusion Cage System	LnK Cervical Interbody Fusion Cage System (Predicate)
1	Manufacturer	L&K BIOMED Co., Ltd.	L&K BIOMED Co., Ltd.
2	Material	PEEK and Tantalum	PEEK and Tantalum
3	510(K) Number	K143360	K120840
4	Product Code	ODP	ODP
5	Class	ClassII	ClassII
6	Intended Use	LnK Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LnK Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.	LnK Cervical Interbody Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LnK Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LnK Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

7. Performance Data

Mechanical performance of additional components of LnK Cervical Interbody Fusion Cage System is same with predicated LnK Cervical Interbody Fusion Cage System(K120840). They are same product in all aspect, except sterilization. Sterilization method is gamma irradiation which is following ISO 11137. It is widely known that gamma irradiation sterilization is not effect on mechanical performance. Therefore, We substitute mechanical test data of additional components of LnK Cervical Interbody Fusion Cage System with it of LnK Cervical Interbody Fusion Cage System(K120840).

The LnK Cervical Interbody Fusion Cage System was tested according to the ASTM F 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing, Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM F 2267.

8. Conclusion

The additional components of LnK Cervical Interbody Fusion Cage System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.