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

October 4, 2016

CG Bio Co., Ltd.
% Ms. April Lee
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K160731
Trade/Device Name: LumFix Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: July 5, 2016
Received: July 11, 2016

Dear Ms. Lee:

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 Parts 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)*
K160731

Device Name
LumFix Spinal Fixation System

Indications for Use *(Describe)*
The LumFix Spinal Fixation System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments 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).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1.	**Manufacturer**	CG Bio Co., Ltd. 244, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea +82-31-732-0840
2.	**Company Contact**	Yuna Jeong (yuna@daewoong.co.kr)
3.	**Official Correspondent**	April Lee Withus Group Inc. Withus6664@gmail.com +1-909-274-9971
4.	**Proprietary Trade Name**	LumFix Spinal Fixation System
5.	**Common Name**	Pedicle Screw Spinal Fixation System
6.	**Classification Name**	888.3070 – Pedicle Screw Spinal System
	Classification	Class II
	Product Codes	MNI, MNH
7.	**Date Prepared**	9/28/2016

General Description

The LumFix Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, set screws, rods and a crosslink linking mechanism.

The LumFix Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. LumFix Spinal Fixation System components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforming to ISO 5832-3 or ASTM F136, with a cobalt-chromium-molybdenum rod option conforming to ASTM F1537 (Co-28Cr-6Mo). Various sizes of these implants are available.

Indications for Use

The LumFix Spinal Fixation System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments 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).

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- Primary Predicate - K093104 Zenius™ Spinal System, Medyssey Co., Ltd.
- Additional Predicate - K132101 ANAX™ 5.5 Spinal System, U&I Corporation

Summary of the Technological Characteristics

The LumFix Spinal Fixation System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. There are slight differences between the length and diameter of screws and rod diameter. But the subject device –LumFix Spinal Fixation System –has similar technological characteristics including design, dimension, intended use, material composition, function and fundamental technologies as predicate devices.

Non-clinical testing

Mechanical testing that was conducted in accordance with ASTM F1717 and ASTM F1798 demonstrates equivalence to the above predicate devices.

Mechanical test reports were completed for the following test methods:

- Static test: Tension, Compression and Torsion test report (ASTM F1717-11)
- Dynamic test: Fatigue test report (ASTM F1717-11)
- Static and fatigue properties (ASTM F1798-13)

Conclusion

Testing and other comparisons have established that the LumFix Spinal Fixation System is substantially equivalent in design, materials, indications, and performance to other predicate devices.