May 25, 2023

CG Bio Co., Ltd.
Iris Kim
Official Correspondent
B1, 1F, 2F, C-dong, 29, Jeyakdanji-ro, Hyangnam-eup
Hwaseong-Si, Gyeonggi-Do 18608
Korea, South

Re: K222229
Trade/Device Name: Advanced LumFix Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: April 28, 2023
Received: April 28, 2023

Dear Iris Kim:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222229

Device Name
Advanced LumFix Spinal Fixation System

Indications for Use *(Describe)*
The Advanced LumFix Spinal Fixation System is intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation): spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and 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.

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3. 510(k) Summary or 510(k) Statement

510(k) Summary

1.	**Manufacturer**	CG Bio Co., Ltd. B1, 1F, 2F, C-dong, 29, Jeyakdanji-ro, Hyangnam-eup Hwaseong-Si, Gyeonggi-Do, Republic of Korea +82-2-550-8300
2.	**Company Contact**	Iris Kim(iriskim@cgbio.co.kr)
3.	**Official Correspondent**	Iris Kim
4.	**Proprietary Trade Name**	Advanced LumFix Spinal Fixation System
5.	**Common Name**	Pedicle Screw Spinal Fixation System
6.	**Classification Name**	888.3070 – Thoracolumbosacral Pedicle Screw System
	Classification	Class II
	Product Codes	NKB
7.	**Date Prepared**	7/20/2022

General Description

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

The Advanced Lumfix Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Advanced 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.

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Predicate Devices

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

- Primary Predicate - K160731: Lumfix Spinal Fixation System, CG Bio Co., Ltd.
- Additional Predicate - K142835: Iliad Pedicle Screw System and Zenius Pedicle Screw System, Medyssey USA
- Additional Predicate - K190471: 4CIS Chiron Spinal Fixation System, Solco Biomedical, Co., Ltd.

Summary of the Technological Characteristics with the Predicate Devices

The Advanced 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 –Advanced Lumfix Spinal Fixation System –has similar technological characteristics including design, 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 F1798 demonstrates equivalence to the above predicate devices.

Mechanical test reports were completed for the following test methods:

- Static test: Compression and Torsion test report (ASTM F1717-11, 18, 21)
- Dynamic test: Compression Fatigue test report (ASTM F1717-11, 18)
- Static Axial Grip, Static Torsional Grip, and Static and Dynamic Transverse Moment (ASTM F1798-13)

Conclusion

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