October 28, 2025

CG MedTech Co., Ltd.
Soli Kim
Regulatory Affairs Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
South Korea

Re: K252351
Trade/Device Name: UniSpace® TPLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 29, 2025
Received: August 21, 2025

Dear Soli 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brent Showalter -S

Brent Showalter, Ph.D.
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)*
K252351

Device Name
UniSpace® TPLIF Cage

Indications for Use *(Describe)*
The UniSpace® TPLIF Cage is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The UniSpace® TPLIF Cage is to be used with supplemental internal spinal fixation. Additionally, the UniSpace® TPLIF Cage is to be used with autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft.

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.

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510(k) Summary

Manufacturer: CG MedTech Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea

Sponsor: CG MedTech Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea

Sponsor Contact: **Soli Kim**, Regulatory Affairs Specialist
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Date Prepared: July 29, 2025–

Device Name: Trade Name: UniSpace® TPLIF Cage

Classification Name: Intervertebral Fusion Device With Bone Graft, Lumbar , per 21 CFR 888.3080

Common Name: Intervertebral Body Fusion Device, IBF Device

Product Code: MAX

Predicate Devices: Velofix™ Interbody Fusion System(K132926)

Additional Predicates: UniSpace® Stand-Alonc C Cage(K234119)
UniSpace™ SA Cervical Cage(K213791)

Description of Device:
The UniSpace® TPLIF Cage is a product for lumbar spinal column stability. The implants of the UniSpace® TPLIF Cage are made of ASTM F3001 titanium alloy (Ti6Al4V ELI) and manufactured using an additive manufacturing method (3D printing), specifically Direct Metal Laser Sintering (DMLS). The UniSpace® TPLIF Cage is available in various heights, widths, lengths, and lordotic angles, and features an open architecture designed to accommodate autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft. The cages are provided in a variety of sizes to accommodate individual patients'

anatomical requirements. The implants of the UniSpace® TPLIF Cage are provided as a sterile pack. The UniSpace® TPLIF Cage is implanted by using instruments manufactured from stainless steel material (ASTM F899) and/or Ti6Al4V ELI (ASTM F136).

Indications For Use:
The UniSpace® TPLIF Cage is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The UniSpace® TPLIF Cage is to be used with supplemental internal spinal fixation. Additionally, the UniSpace® TPLIF Cage is to be used with autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft.

Substantial Equivalence:
UniSpace® TPLIF Cage is substantially equivalent to Velofix™ Interbody Fusion System(K132926) in design, mechanical performance, function and intended use.

The mechanical performance of UniSpace® TPLIF Cage falls within the acceptance criteria which have been established from the predicate devices.

1. Comparison Technological Characteristics
The predicate and proposed devices have similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- The similar design features
- The equivalent mechanical performance

The first difference between the UniSpace® TPLIF Cage and predicate deivces is the sterilization method. While the predicate device is provided non-sterile, the UniSpace® TPLIF Cage is gamma-sterile and provided sterile pack. But, gamma sterilization conditions of UniSpace® TPLIF Cage is justified for the comparison with reference device(UniSpace® Stand-Alonc C Cage – K234119) . And, Mechanical safety after 5-year accelerated aging of UniSpace TPLIF® Cage is justified for the comparision with reference deivce(UniSpace™ SA Cervical Cage - K213791). This difference does not raise any issues of safety or effectiveness.

The second difference between the UniSpace® TPLIF Cage and predicate devices is in the raw material. UniSpace® TPLIF Cage are made of titanium alloy (Ti6Al4V ELI) in accordance with ASTM F3001, while the predicate device is made of polyether-ether-ketone(PEEK) in accordance with ASTM F2026 and tatalum in accordance with ASTM F560. This difference does not raise any issues of safety or effectiveness. Performance data demonstrate that the UniSpace® TPLIF Cage is as safe and effective as its predicate devices. Thus, the UniSpace® TPLIF Cage and predicate devices are substantially equivalent.

2. Performance Testing

The UniSpace® TPLIF Cage was tested in a non-clinical setting (bench testing) to assess that no new safety and effectiveness issues were raised with this device. The testing meets all acceptance criteria and verifies that performance of the UniSpace® TPLIF Cage is substantially equivalent to the predicate devices.

The following tests were performed:

(1) Static compression test according to ASTM F2077
(2) Static compression shear to ASTM F2077
(3) Dynamic compression test to ASTM F2077
(4) Dynamic compression shear to ASTM F2077
(5) Subsidence test to ASTM F2267

3. Conclusion

The data and information provided in this submission support the conclusion that the UniSpace® TPLIF Cage is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.