August 5, 2022

Edisoninno Co., Ltd.
So-Yeon Jang
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do
11781 South Korea

Re: K213791
Trade/Device Name: Unispace™ SA Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: June 28, 2022
Received: July 6, 2022

Dear So-Yeon Jang:

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,

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)*
K213791

Device Name
UniSpace™ SA Cervical Cage

Indications for Use *(Describe)*
The UniSpace™ SA Cervical Cage is a standalone anterior cervical interbody fusion device indicated for skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The UniSpace™ SA Cervical Cage implants are to be used with either autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an open, anterior approach.
The cage of the UniSpace™ SA Cervical Cage must be used with the two internal fixation screws provided. UniSpace™ SA Cervical Cage implants with ≥ 20° lordosis must be used with an additional supplemental fixation system that has been cleared by the FDA for use in the cervical spine," in addition to the two integrated fixation screws provided.
This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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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K213791
510(k) Summary

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

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

Sponsor Contact: **So-Yeon Jang**, RA specialist
+82 31 860 6836
soyeon@edisoninno.co.kr

Date Prepared: **June 28, 2022**

Device Name: Trade Name: UniSpace™ SA Cervical Cage

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

Common Name: Intervertebral Body Fusion Device, IBF Device

Product Code: OVE, ODP

Predicate Devices: EIT Cellular Titanium® Cervical Cage (K201605, Primary)
Galaxy (ACIF, PLIF, TLIF and ALIF) Peek cage
(K122872) Velofix™ Interbody Fusion System (K190067)
Velofix™ SA Cervical Cage (K172424)
3d Cage™ (K180347)

Description of Device:

The UniSpace™ SA Cervical Cage is product for cervical spinal column stability. The implants of the UniSpace™ SA Cervical Cage consist of the cages manufactured through additive manufacturing (ASTM F3001) and the machined variable screws and locking cover plate (ASTM F136). The locking cover plate consists of a locking plate and a locking screw and is an optional device for the anti-backout of the variable screw. This optional implant can provide the more stability to prevent the anti-backout besides the self-locking mechanism. The cages and variable screws are offered in a variety of sizes to accommodate each patient's individual clinical case. The cages are designed to be used with either autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The cage of the UniSpace™ SA Cervical Cage is provided as a sterile pack. The UniSpace™ SA Cervical Cage is implanted by using the instruments manufactured from stainless steel material that conform to ASTM F899.

Indications For Use:

The UniSpace™ SA Cervical Cage is a standalone anterior cervical interbody fusion device indicated for skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The UniSpace™ SA Cervical Cage implants are to be used with either autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an open, anterior approach. The cage of the UniSpace™ SA Cervical Cage must be used with the two internal fixation screws provided. UniSpace™ SA Cervical Cage implants with ≥ 20° lordosis must be used with an additional supplemental fixation system that has been cleared by the FDA for use in the cervical spine, in addition to the two integrated fixation screws provided.This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Substantial Equivalence:

UniSpace™ SA Cervical Cage is substantially equivalent to EIT Cellular Titanium® Cervical Cage (K201605), Galaxy ACIF Peek cage (K122872), Velofix™ Interbody Fusion System (K190067), Velofix™ SA Cervical Cage (K172424) in design, material, mechanical performance, function and intended use.

The mechanical performance of UniSpace™ SA Cervical Cage falls within the acceptance criteria which have been established from the predicate devices.

1. Comparison Technological Characteristics

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

The predicate device 3D Cage™ (K180347) and the proposed device has the same AM process.

2. Performance Testing

The UniSpace™ SA Cervical 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™ SA Cervical Cage is substantially equivalent to the predicate devices. The reference device 3D Cage™ (K180347) has the intended use for lumbar fusion, therefore its performance evaluation cannot be compared to the proposed device.

The following tests were performed:

1) UniSpace™ SA Cervical Cage
   (1) Static compression test according to ASTM F2077
   (2) Static torsion test according to ASTM F2077
   (3) Static compression shear to ASTM F2077
   (4) Dynamic compression test to ASTM F2077
   (5) Dynamic torsion test to ASTM F2077
   (6) Dynamic compression shear to ASTM F2077
   (7) Subsidence test to ASTM F2267
   (8) Torsional properties test to ASTM F543
   (9) Axial pullout test to ASTM F543*1)
   (10) Driving Torque test to ASTM F543*1)

*1) The thread geometry and diameter are dominant factors for the pull-out strength, driving and removal torque test. The variable screws of the proposed UniSpace™ SA Cervical Cage have the same specifications including thread geometry, diameters, postprocessing, etc. as the predicate device (Velofix™ SA Cervical Cage, 510K No.: K172424) except for the head shape. Thus, The test result(test item: Axial pullout test, Driving torque test) of Velofix™ SA Cervical Cage is applicable to the screws of UniSpace™ SA Cervical Cage. Only the test performed for the screws of UniSpace™ SA Cervical Cage is torsional properties test as per ASTM F543.
The complete test report for Velofix™ SA Cervical Cage(RE-TS01-170724) is provided in Exhibit 5.

3. Conclusion

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