April 19, 2024

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

Re: K234119
Trade/Device Name: UniSpace® Stand-Alone C Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: March 28, 2024
Received: March 28, 2024

Dear Chae-Hyeon 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.

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,

Katherine D. Kavlock -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234119

Device Name

UniSpace® Stand-Alone C Cage

Indications for Use *(Describe)*

The UniSpace® Stand-Alone C 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® Stand-Alone C 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 Cages of the UniSpace® Stand-Alone C Cage must be used with the two internal fixation screws provided. The Cages 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"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

Manufacturer:	Innosys Co., Ltd. 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea
Sponsor:	Innosys Co., Ltd. 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea
Sponsor Contact:	**Chae-Hyeon Kim**, Regulatory Affairs Specialist +82 31 860 6836 ch.kim@inno-sys.net
Date Prepared:	**March 28, 2024**
Device Trade Name:	UniSpace® Stand-Alone C 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
Predicate Devices:	UniSpace™ SA Cervical Cage (K213791)
Reference Device:	Aspiron™ S ACP System (K220147) Velofix™ SA Cervical Cage (K172424)

Description of Device:

The UniSpace® Stand-Alone C Cage is product for cervical spinal column stability. The implants of the UniSpace® Stand-Alone C Cage consist of the Cages manufactured through additive manufacturing (ASTM F3001) and the machined Variable screws and Locking plates (ASTM F136). The Locking plate consists of a Blocking plate and a Locking screw and is an additional device for the anti-backout of the Variable screw. This optional implant can help users who feel uncomfortable with the primary self-locking mechanism or when rescue screws are utilized. The Cages and Variable screws are provided 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 Cages of the UniSpace® Stand-Alone C Cage are provided as a sterile pack. The UniSpace® Stand-Alone C Cage is implanted by using the instruments manufactured from stainless steel material that conform to ASTM F899.

Indications For Use:
The UniSpace® Stand-Alone C 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® Stand-Alone C 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 Cages of the UniSpace® Stand-Alone C Cage must be used with the two internal fixation screws provided. The Cages 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® Stand-Alone C Cage is substantially equivalent to UniSpace™ SA Cervical Cage (K213791) in design, material, mechanical performance, function and intended use.

The mechanical performance of UniSpace® Stand-Alone C 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 same indications for use
- The similar design features
- The same materials
- The equivalent mechanical performance

2. Performance Testing

The UniSpace® Stand-Alone C 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® Stand-Alone C Cage is substantially equivalent to the predicate devices and reference devices.

The following tests were performed:

1) UniSpace® Stand-Alone C 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) Axial pullout test to ASTM F543
   (9) Torsional properties test to ASTM F543
   (10) Driving Torque test to ASTM F543
   (11) Locking band strength test to ASTM F04-25-02-02, ASTM F543
   (12) Locking plate strength test to ASTM F04-25-02-02, ASTM F543
   (13) Torsional strength test for Locking screw to ASTM F543

3. Conclusion

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