



July 23, 2026

FIMS Co., Ltd.
Lee Jiyeon
Primary Applicant
2F, 56, Changnyong-Daero 256beon-Gil
Yeongtong-Gu
Suwon-Si, Gyeonggi-do
South Korea

Re: K253041
Trade/Device Name: 3d Cage Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 25, 2026
Received: June 25, 2026

Dear Lee Jiyeon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

510(k) Number (if known)

K253041

Device Name

3d Cage Cervical

Indications for Use (Describe)

The 3d Cage Cervical are intervertebral body fusion devices indicated for use with autograft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non operative treatment. The 3d Cage Cervical are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	FIMS Co., Ltd.
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Applicant Contact	Ms. Lee Jiyeon
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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	3d Cage Cervical
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170503	EIT Cellular Titanium ® Cervical Cage	ODP

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The 3d Cage Cervical is a cervical interbody fusion device used in anterior cervical fusion surgery. Its open truss design provides structural support while creating space for bone growth and fusion. Available in various sizes to accommodate different anatomical structures, it includes a window for bone grafting. Manufactured from Ti-6Al-4V ELI material using Selective Laser Melting (SLM) technology, the 3d Cage Cervical is provided in a sterile condition.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The 3d Cage Cervical are intervertebral body fusion devices indicated for use with autograft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non operative treatment. The 3d Cage Cervical are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indication for use of the subject device and predicate device are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device is a 3D-printed cervical interbody fusion cage. Both the subject device and the predicate device are composed of

100% titanium alloy and are intended for use in patients with cervical disc diseases (DDD). Since the subject device and the predicate device are identical in raw material, manufacturing process, intended use, mode of action, and method of use, the two devices can be considered substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

The Performance test of 3d Cage Cervical was performed according to ASTM F2077 Standard Test Methods for Intervertebral Body Fusion Devices, including static and dynamic axial compression, compression shear, and torsion, and ASTM F2267 Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression. These standards are well established test methods for Cervical Cages. Test results were compared to both tests of the predicate device and to published data.

The raw material of 3D Cage Cervical and predicate device is titanium powder ASTM F3001 (Ti6Al4V ELI).

The difference between 3d Cage Cervical and predicated devices are the product shape and slight mechanical and physical characteristics. However, the slight differences do not affect to the application of the devices.

Therefore, we state that 3d Cage Cervical are substantially equivalent to the predicate device.