October 28, 2019

FIMS Co., Ltd.
Younggwang Choi
RA Team Staff
B1, 440, Ghangnyong-daero, Yeongtong-gu
Suwon-si, Gyeonggi-do 16229
Korea

Re: K180347
Trade/Device Name: 3d Cage™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 18, 2019
Received: October 23, 2019

Dear Younggwang Choi:

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,

for Ronald P. Jean, PhD
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180347

Device Name
3d Cage™

Indications for Use *(Describe)*
The 3d Cage is an intervertebral body fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy. The device is indicated to be used with a supplemental fixation system and autograft bone.

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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510(k) Summary

10/24/2019

1. Company

	Submitter
Name	FIMS Co., Ltd.
Address	B1, 440, Changnyong-daero, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea Rep.
Phone/Fax	+82-70-7098-6352/ +82-31-261-8649
Contact person	Younggwang Choi / RA ygchoi@genoss.com
Summary Date	10/24/2019

2. Device Name

Proprietary name: 3d Cage™
Regulation number: 21 CFR 888.3080
Classification name: Intervertebral fusion device with Bone Graft, Lumbar
Product code: MAX
Device class: Class II

3. Predicated Device

1) Primary Predicated device

K170503 EIT Cellular Titanium ® PLIF CAGE, TLIF CAGE

2) Additional Predicated device

K111820 SYNSTER® (CERVICAL, ALIF, PLF, PTLIF and TLIF)Cage

K171351 Posterior Spine Truss System (PSTS) Interbody Fusion Device

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4. Description

3d Cage™ is an intervertebral body fusion cage intended for use in (Posterior/Transforaminal) lumbar spinal fixation procedures. It is an open architecture truss designed to provide effective structural support with open space throughout the implant for bone growth and fusion.
The cage is provided sterile and constructed from titanium alloy (Ti-6Al-4V, ASTM F3001) using Selective Laser Melting (SLM) method.

5. Indication for use

The 3d Cage is an intervertebral body fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy. The device is indicated to be used with a supplemental fixation system and autograft bone.

6. Technological Characteristics

The purpose of this premarket notification is to obtain clearance to market the
3d Cage™ is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The 3d Cage™ Implant components are made of titanium 6-aluminum 4-vanadium alloy that conforms to ASTM F3001.
The subject system has similar technological characteristics as the predicate devices identified above.
Substantially equivalent result of non-clinical testing relative static and dynamic testing (per ASTM F2077-18, 14), subsidence testing (per ASTM F2267-04).

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7. Performance Data

The worst-case device was tested in static and dynamic compression, static and dynamic compression shear (ASTM F2077) and subsidence (ASTM F2267).

Review

FIMS 3d Cage™ have the similar technological characteristics as the predicate device; including the material, indication for use, and design.

8. Conclusion

Based on the information provided in this premarket notification of FIMS Co., Ltd. concludes that FIMS 3d Cage™ are substantially equivalent to predicate devices.