



Solco Biomedical Co., Ltd.
% Hwi-geun Yu
Manager
154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do,
17704, Republic of Korea

September 18, 2019

Re: K190563

Trade/Device Name: 4CIS® PEEK PLIF Cage, 4CIS® Pebble Beach PEEK PLIF Cage, 4CIS® Torrey Pines PEEK TLIF Cage, 4CIS® Dunes PEEK DLIF Cage, 4CIS® Augusta PEEK ALIF Cage

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX

Dated: August 14, 2019

Received: August 19, 2019

Dear Hwi-geun Yu:

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
Melissa Hall
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K190563

Device Name

Spinal Fusion Cage System (4CIS® PEEK PLIF Cage, 4CIS® Pebble Beach PEEK PLIF Cage, 4CIS® Torrey Pines PEEK TLIF Cage, 4CIS® Dunes PEEK DLIF Cage, 4CIS® Augusta PEEK ALIF Cage)

Indications for Use (Describe)

The Spinal Fusion Cage System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Spinal Fusion Cage System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months 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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510(k) Summary

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| Submitter | <p>Solco Biomedical Co., Ltd.</p> <p>154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 17704 Republic of Korea</p> <p>Phone. +82-31-664-4101</p> <p>Fax. +82-31-663-8983</p> |
| Contact Person | <p>Hwi-geun Yu</p> <p>154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 17704 Republic of Korea</p> <p>Phone: +82)31-610-4091</p> <p>Fax: +82)31-663-8983</p> |
| Submission Date | Mar 01, 2019 |
| Trade / Proprietary name | Spinal Fusion Cage System (4CIS [®] Augusta PEEK ALIF Cage, 4CIS [®] Dunes PEEK DLIF Cage, 4CIS [®] Torrey Pines PEEK TLIF Cage, 4CIS [®] Pebble Beach PEEK PLIF Cage, 4CIS [®] PEEK PLIF Cage) |
| Common / Usual Name | Spinal Fusion Cage System |
| Classification Name | Intervertebral body fusion device with bone graft, lumbar |
| Classification Code | MAX |
| Regulatory Class | Class II |
| Regulation Number | 888.3080 |
| Predicate Device | <p>4CIS[®] PEEK PLIF and TLIF Cage System (K092162, SE 01/06/2010) [Solco Biomedical Co., Ltd.] – Primary Predicate</p> <p>PATRIOT[™] Spacers (Continental[™] ALIF Spacer, TransContinental[™] LLIF Spacer) (K072970, SE 01/18/2008) [GLOBUS MEDICAL, INC.] – Additional Predicate</p> <p>ARDIS SPACER (K073202, SE 01/30/2008) [ABBOTT SPINE, INC.] – Additional Predicate</p> |

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| Description of Device | <p>The Spinal Fusion Cage System is single component devices used to restore height of disc space via posterior, lateral, anterior, oblique approach and to facilitate lumbar intervertebral body fusion with maintaining physiological lordotic angulation of lumbar spine. To allow maximum preservation and ensure ample contact surfaces with bony endplate, a variety of shapes and sizes are available and each device has tantalum (ASTM F560) markers for ease of visualization on radiographs. Vertical square teeth on the top and the bottom surface prevent subsidence of the cage into the vertebral body while they increase the anchoring and prevent slipping or expulsion. To make solid fusion of intervertebral body, hollow space in the implant allows autologous bone graft material to be filled. The implant has safety proven structure and material (Polyetheretherketone, ASTM F2026) to promote biological synostosis and assures mechanical safety against load.</p> |
| Indication for Use | <p>The Spinal Fusion Cage System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Spinal Fusion Cage System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months of non-operative treatment.</p> |
| Comparison of Technological Characteristics with the Predicate Devices | <p>The subject device and all the predicates have the same or similar indications for use statements. The subject device is composed of the same material as the predicate devices conforming to recognized industry standards for permanent implants and surgical orthopedic instruments. All they have similar basic design features and functions as well as those dimensions. The subject device and cited predicate devices are provided non-sterile for single use only. The subject device demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.</p> |
| Performance Data | <p>Mechanical testing (static axial compression, static compression-shear, static subsidence and dynamic axial compression) was conducted in accordance with ASTM F2077-14 and F2267-04.</p> <p>Above non-clinical performance data in the form of a comprehensive literature review was provided in support of substantial equivalence of the subject device.</p> |

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| Conclusion | The overall technology characteristics and mechanical performance data lead to the conclusion that the subject device is substantially equivalent to legally marketed predicate devices. |
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