December 19, 2019

Solco Biomedical Co., Ltd.
Hwi-Geun Yu
RA & Exam Certification Team Leader
154 Seotan-ro, Seotan-myeon
Pyeongtaek-Si, Gyeonggi-do, 17704
Republic of Korea

Re: K192044
Trade/Device Name: 4CIS Marlin PEEK ACIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 29, 2019
Received: December 4, 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,

Brent L. Showalter, PhD
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.

K192044

Device Name

4CIS® Marlin PEEK ACIF Cage

Indications for Use *(Describe)*

4CIS® Marlin PEEK ACIF Cage is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels 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 patient history and radiographic studies. These patients should have six weeks of non-operative therapy in advance. The 4CIS® Marlin PEEK ACIF Cage is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach. It is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine, such as Anterior Cervical Plate system.

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

Submitter	Solco Biomedical Co., Ltd. 154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 17704 Republic of Korea Phone. +82-31-664-4101 Fax. +82-31-663-8983
Contact Person	Hwi-geun Yu Solco Biomedical Co., Ltd. 154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 17704 Republic of Korea Phone: +82)31-610-4091 Fax: +82)31-663-8983
Preparation Date	July 22, 2019
Trade / Proprietary name	4CIS® Marlin PEEK ACIF Cage
Common / Usual Name	Cervical Intervertebral Body Fusion Device
Classification Name Classification Code Regulatory Class Regulation Number	Intervertebral Fusion Device With Bone Graft, Cervical ODP Class II 888.3080

Predicate Device	4CIS® Marlin ACIF Cage System (K162402) [Solco Biomedical Co., Ltd.] – Primary Predicate PATRIOT SPACERS: COLONIAL ACDF (K072991, Additional) TRYPTIK Ca (K091873, Additional) MATISSE Anterior Cervical Interbody Fusion Cage System (K162682, Additional)
Description of Device	4CIS® Marlin PEEK ACIF Cage is single component devices used to restore height of disc space by anterior approach and to facilitate cervical interbody fusion with maintaining physiological lordotic angulation of cervical 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 three tantalum markers for ease of visualization on radiographs. The 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 bone graft material to be filled. The implant has safety proven structure and material (Poly-ether-ether-ketone, ASTM F2026) to promote biological synostosis and assures mechanical safety against load.
Indication for Use	4CIS® Marlin PEEK ACIF Cage is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels 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 patient history and radiographic studies. These patients should have six weeks of non-operative therapy in advance. The 4CIS® Marlin PEEK ACIF Cage is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach. It is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine, such as Anterior Cervical Plate system.

Comparison of Technological Characteristics with the Predicate Devices	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.
Performance Data	Mechanical testing (static axial compression, static compression-shear, static torsion, dynamic axial compression, dynamic compression-shear, dynamic torsion and static subsidence) was conducted in accordance with ASTM F2077-17 and F2267-04. Above non-clinical performance data in the form of a comprehensive literature review was provided in support of substantial equivalence of the subject device.
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.