DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 16, 2017

Solco Biomedical Co., Ltd.
℅ Hwi Joon Park
Manager
First Gold Corp.
14110 Dallas Pkwy, Suite 135
Dallas, Texas 75254

Re: K162402
Trade/Device Name: 4CIS® Marlin ACIF Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 11, 2016
Received: January 17, 2017

Dear Mr. Park:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162402

Device Name
4CIS® Marlin ACIF Cage System

Indications for Use *(Describe)*

4CIS® Marlin ACIF Cage System is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels from 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. The 4CIS® Marlin ACIF Cage System 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 JOON, PARK 14110 Dallas Pkwy Suite 135, Dallas, Texas 75254 USA Phone: +1-972-247-2486 Fax: +1-972-247-2413
Submission Date	Aug 23, 2016
Trade / Proprietary name	4CIS® Marlin ACIF Cage System
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	SYNTHES ACIS/VERTEBRAL SPACER CR (K120275, Primary) Endoskeleton® TC (K100889, Additional) PATRIOT SPACERS: COLONIAL ACDF(K072991, Additional) Phantom™ Plus (K082801, Additional) TRYPTIK Ca (K091873, Additional) The predicate devices have not been subject to a design related recall.
Description of Device	4CIS® Marlin ACIF cages are hollow, generally rectangular box shape made either from poly-ether-ether-ketone [PEEK-OPTIMA® LT1 (Invibio, Inc., West Conshohocken, PA USA) / VESTAKEEP® i4R (Evonik Industries, Essen Germany)] or Titanium alloy according to ASTM F2026(PEEK), F136(64ELI), F560(Tantalum). The cages are available in a variety of sizes and geometric options to

	fit the anatomical needs of a wide variety of patients. The device is filled with a bone graft material and inserted into the intervertebral body space of the cervical spine through an anterior cervical approach. As the design requirements, this cage design maintains the spacing between two vertebral bones following discectomy until fusion occurs. Each PEEK cage has three(3) x-ray markers made of tantalum for ease of visualization on the radiographs. Angled shape for lordotic curve and anatomic shape is available to allow maximum preservation of bony endplate with this system and teeth on the surfaces ensure enough contact with bony endplate, which prevents subsidence of the cage into the vertebral body when the teeth increase the anchoring and prevent slipping or expulsion.
Indication for Use	4CIS® Marlin ACIF Cage System is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels from 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. The 4CIS® Marlin ACIF Cage System 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	**Indication for Use** The subject 4CIS® Marlin ACIF Cage System and all the predicates have similar indications for use statements. **Materials** The predicate subject device is composed of the same material as the predicate devices have conforming to recognized industry standards for permanent implants. **Design Features/Functions** The subject 4CIS® Marlin ACIF Cage System and cited predicate devices share similar basic design features and functions. **Dimensions** The subject 4CIS® Marlin ACIF Cage System is dimensionally similar to cited predicate devices. **Sterilization** The subject 4CIS® Marlin ACIF Cage System and cited predicate devices are provided sterile and non-sterile for single use only. **Performance Specification**

	Mechanical testing confirmed 4CIS® Marlin ACIF Cage System demonstrated equivalent performance to the cited predicate device under the same test conditions.
Performance Data	Mechanical testing (static and dynamic compression, static and dynamic torsion, static subsidence and static expulsion) was conducted in accordance with ASTM F2077, and ASTM F2267. 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	Based on the provided performance data, the subject device is substantially equivalent to the referenced predicate devices.