January 16, 2019

Solco Biomedical Co., Ltd.
% Mr. Hwi Joon Park
Manager
First Gold Corporation
14110 Dallas Parkway, Suite 135
Dallas, Texas 75254

Re: K182489
Trade/Device Name: 4CIS® Pinehurst Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 18, 2018
Received: December 20, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182489

Device Name
4CIS® Pinehurst Anterior Cervical Plate system

Indications for Use *(Describe)*
The 4CIS® Pinehurst Anterior Cervical Plate system is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) Spondylolisthesis, 3) trauma (including fractures), 4) Spinal Stenosis, 5) tumors, 6) deformity (defined as kyphosis, lordosis, or scoliosis), 7) pseudarthrosis, and/or 8) failed previous fusions.

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	Sep 04, 2018
Trade / Proprietary name	4CIS® Pinehurst Anterior Cervical Plate system
Common / Usual Name	Intervertebral body fixation orthosis
Classification Name Classification Code Regulatory Class Regulation Number	Spinal Intervertebral Body Fixation Orthosis KWQ Class II 888.3060
Predicate Device	Zevo™ Anterior Cervical Plate System (K141632, SE 12/04/2014) [MEDTRONIC SOFAMOR DANEK USA, INC.] – Primary Predicate Anterior Cervical Spine Locking Plate (CSLP) System (K792352, SE 12/06/1979) [DEPUY SYNTHES] – Additional Predicate Anterior Cervical Spine Locking Plate (CSLP) System (K926453, SE 10/12/1993) [SYNTHES(USA)] – Additional Predicate IST ANTERIOR CERVICAL PLATE SYSTEM (K072650, SE 11/28/2007) [INNOVATIVE SPINAL TECHNOLOGIES INC] – Additional Predicate

Description of Device	The 4CIS® Pinehurst Anterior Cervical Plate system is intended for anterior cervical intervertebral body screw fixation from C2 to T1. Rigid fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. Implant components consist of a variety of shapes and sizes of plates, bone screws and associated instruments. Locking caps are pre-assembled to the plates. They cover the heads of the bone screws to reduce the potential for screw back-out. With this locking mechanism, implant components can be rigidly locked into many different configurations to suit the individual pathology and anatomical conditions of the mature patient. They are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136. Implants must not be used with the components from any other system or manufacturer in a construct.
Indication for Use	The 4CIS® Pinehurst Anterior Cervical Plate system is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) Spondylolisthesis, 3) trauma (including fractures), 4) Spinal Stenosis, 5) tumors, 6) deformity (defined as kyphosis, lordosis, or scoliosis), 7) pseudarthrosis, and/or 8) failed previous fusions.
Comparison of Technological Characteristics with the Predicate Devices	**Indication for Use** The subject 4CIS® Pinehurst Anterior Cervical Plate system and all the predicates have the same or similar indications for use statements. **Materials** 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. **Design Features/Functions** The subject 4CIS® Pinehurst Anterior Cervical Plate system and cited predicate devices share similar basic design features and functions. **Dimensions** The subject 4CIS® Pinehurst Anterior Cervical Plate system is dimensionally similar to cited predicate devices. **Sterilization** The subject 4CIS® Pinehurst Anterior Cervical Plate system and cited predicate devices are provided non-sterile for single use only. **Performance Specification** Mechanical testing confirmed 4CIS® Pinehurst Anterior Cervical Plate system demonstrated equivalent performance to the cited predicate device under the same test conditions.

Performance Data	Mechanical testing (static and dynamic compression bending, static tension bending, static torsion) was conducted in accordance with ASTM F1717. 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 4CIS® Pinehurst Anterior Cervical Plate system is substantially equivalent to legally marketed predicate devices for intended use, material composition, principles of operation, and design.