July 24, 2019

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

Re: K190471
Trade/Device Name: 4CIS® Chiron Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 8, 2019
Received: July 11, 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,

Ronald P. Jean, Ph.D.
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

Indications for Use

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

510(k) Number *(if known)*
K190471

Device Name

4CIS® Chiron Spinal Fixation System

Indications for Use *(Describe)*

The 4CIS® Chiron Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis; and failed previous fusion (pseudoarthrosis).

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-si, 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-si, Gyeonggi-do, 17704 Republic of Korea Phone: +82)31-610-4091 Fax: +82)31-663-8983
Submission Date	Feb 22, 2019
Trade / Proprietary name	4CIS® Chiron Spinal Fixation System
Common / Usual Name	Spinal Fixation System
Classification Name Classification Code Regulatory Class Regulation Number	Thoracolumbosacral pedicle screw system NKB Class II 888.3070
Predicate Device	EXPEDIUM SPINE SYSTEM, VIPER SYSTEM, VIPER 2 SYSTEM (K111136) [DEPUY SPINE, INC.] – Primary Predicate MOSS MIAMI SPINAL SYSTEM (K030383) [DEPUY AcroMed Inc.] – Reference Predicate SYNERGY™ TI INTEGRAL OPEN SCREW SYSTEM (K012871) [Interpore Cross International, LLC] – Reference Predicate

Description of Device	The Spinal Fixation System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, nuts, transverse (cross) link and associated instruments. Rigid fixation is provided by pedicle screws inserted into the vertebral body through pedicle of the lumbar spine via posterior approach. This system will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion through open surgery or minimally invasive surgery. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the mature patient. The implant components are supplied non-sterile single use and are fabricated from titanium alloy (Ti-6A1-4V ELI) that conforms to ASTM F 136 and CoCr Alloy per ASTM F1537. Also, Specialized instruments are available for the application and removal of the Spinal Fixation System.
Indication for Use	The 4CIS® Chiron Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis; and failed previous fusion (pseudoarthrosis).
Comparison of Technological Characteristics with the Predicate Devices	The 4CIS® Chiron Spinal Fixation System and all the predicates have the same or similar indications for use statements. The system is composed of the same material as the predicate devices conforming to recognized industry standards for permanent implants and surgical orthopedic instruments. The 4CIS® Chiron Spinal Fixation System and cited predicate devices share similar basic design features and functions as well as their dimensions. Also they are provided non-sterile for single use only. Mechanical testing confirmed the 4CIS® Chiron Spinal Fixation 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 to the predicate devices.
Conclusion	The overall technology characteristics and mechanical performance data lead to the conclusion that Spinal Fixation System is substantially equivalent to legally marketed predicate devices for intended use, material composition, principles of operation, and design.