Solco Biomedical Co., Ltd.
Seo-Hee Koo
RA & Exam Certification Team Researcher
154 Seotan-ro, Seotan-myeon
Pyeongtaek-Si, 17704
South Korea

November 26, 2024

Re: K231655
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, KWP
Dated: October 28, 2024
Received: October 28, 2024

Dear Seo-Hee Koo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.11.26 13:56:02 -05'00'

for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231655

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:
1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis
3. Trauma (i.e., fracture or dislocation)
4. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
5. Tumor
6. Stenosis
7. 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.

5. 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	Seo-Hee Koo Solco Biomedical Co., Ltd. 154 Seotan-ro, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 17704 Republic of Korea Phone: +82)31-610-4079 Fax: +82)31-663-8983
Submission Date	May 25, 2023
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, KWP Class II 888.3070

Predicate Device	4CIS® Chiron Spinal Fixation System (K203233)[Solco Biomedical Co., Ltd.] – Primary Predicate EXPEDIUM SPINE SYSTEM, VIPER SYSTEM, VIPER 2 SYSTEM (K111136) [DEPUY SPINE, INC.] – Additional Predicate MOSS MIAMI SPINAL SYSTEM (K030383) [DEPUY AcroMed Inc.] – Additional Predicate SYNERGY™ TI INTEGRAL OPEN SCREW SYSTEM (K012871) [Interpore Cross International, LLC] – Additional Predicate LDR Spine Easyspine Posterior Spinal System (K123134) [LDR Spine USA] – Additional Predicate
Description of Device	The 4CIS® Chiron 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 Cobalt Alloy (Co-28Cr-6Mo) per ASTM F1537. Also, 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: 1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); 2. Spondylolisthesis;

	3. Trauma (i.e., fracture or dislocation); 4. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); 5. Tumor; 6. Stenosis; 7. 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 was performed including static and dynamic compression bending and static torsion testing per ASTM F1717 as well as axial and torsional grip testing and tulip-dissociation testing per ASTM F1798.
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.