Solco Biomedical Company India Private Limited
Darshak Shah
Director
Survey No.1540, Beside Torrent Pharma, Village-Rajpur
Ahmedabad Mehsana Highway, Ta-Kadi, Dist-Mehsana
Gujarat 382715
India

February 18, 2021

Re: K202498
Trade/Device Name: 4CIS SARA Spine System, 4CIS VERTU Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: December 30, 2020
Received: January 6, 2021

Dear Darshak Shah:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202498

Device Name

4CIS SARA Spine System,
4CIS VERTU Spine System

Indications for Use *(Describe)*

The 4CIS SARA Spine System and 4CIS VERTU Spine System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the 4CIS SARA Spine System and 4CIS VERTU Spine 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 Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

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"

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirement of 21 CFR 807.92.

Submitter	SOLCO Biomedical Company India Private Limited Survey No.1540, Beside Torrent Pharma, Village-Rajpur Ahmedabad Mehsana Highway, Ta-Kadi, Dist-Mehsana Gujarat- 382715, INDIA. Tel : +91 851112597, Email: darshak@solco.co.in
Contact Person	Darshak Shah- Director SOLCO Biomedical Company India Private Limited Phone : +91 98252 06091, Email: darshak@solco.co.in
Submission Date	December 21, 2020
Trade / Proprietary name	4CIS SARA Spine System 4CIS VERTU Spine Sytem
Classification Name Classification Code Regulatory Class Regulation Number	Thoracolumbosacral Pedicle screw system NKB Class II 21 CFR 888.3070
Predicate Device	**510K Number** / **Trade or Proeprty or model Name** / **Manufacturer** K102458 (Primary) / 4CIS® SOLAR Spine System / Solco Biomedical Co., Ltd.-Korea K030383 (Reference) / Moss Miami Spinal System / DePuy AcroMed
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. 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) and Cobalt Chromium alloy that conforms to ASTM F136 and ASTM F1537 respectively. Also, Specialized instruments are available for the application and removal of the Spinal Fixation System.
Indications for Use	The 4CIS SARA Spine System and 4CIS VERTU Spine System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the 4CIS SARA Spine System and 4CIS VERTU Spine 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 Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).
Comparison of Technological Characteristics	The 4CIS SARA Spine System and 4CIS VERTU Spine 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 (Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136) and surgical orthopedic instruments. 4CIS SARA Spine System, 4CIS VERTU Spine 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.

Performance Data	Mechanical testing (static and dynamic compression bending, static tension bending, static torsion) is conducted in accordance with ASTM F1717. Static Tension Test, Static Torsion test, Static Compression test & Dynamic Compression bending test (Fatigue Test) meets performance requirement against predicates.
Conclusion	The overall technology characteristics, material of construction, design characteristics and performance data lead to the conclusion that our Spine Systems (4CIS SARA Spine System and 4CIS VERTU Spine System) is substantially equivalent to legally marketed predicate devices for intended use, material composition, principles of operation, and design.