December 19, 2022

SOLCO Biomedical Company India Private Limited
Darshak Shah
Director
5 & 6 Third Floor, B Jadav Chambers, Above Sales India
Ahmedabad, Gujarat 380009
India

Re: K213653
Trade/Device Name: 4CIS BLACK MARLIN PLIF CAGE SYSTEM, 4CIS DOLPHIN TLIF CAGE SYSTEM
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 7, 2022
Received: December 12, 2022

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,

Katherine D. Kavlock -S

for
Brent Showalter, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213653

Device Name
4CIS BLACK MARLIN PLIF CAGE SYTEM
4CIS DOLPHIN TLIF CAGE SYSTEM

Indications for Use *(Describe)*
The Spinal Fusion Cage System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Spinal Fusion Cage System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months of nonoperative treatment.

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 isbeing submitted in accordacne with requirement of 21 CFR 807.92.

<table>
<tr><td>Submitter</td><td>SOLCO Biomedical Company India Private Limited
Survey No.1540, Beside Torrent Pharma, Village-Rajpur
Ahmedabad Mehsana Highway, Ta-Kadi, Dist-Mehsana
Gujarat- 382715, INDIA.</td></tr>
<tr><td>Contact Person</td><td>Darshak Shah
Director
SOLCO Biomedical Company India Private Limited
Phone : +91 98252 06091, Email: darshak@solco.co.in</td></tr>
<tr><td>Submission Date</td><td>Thursday, December 15, 2022</td></tr>
<tr><td>Trade / Proprietary name</td><td>4CIS BLACK MARLIN PLIF CAGE SYSTEM
4CIS DOLPHIN TLIF CAGE SYSTEM</td></tr>
<tr><td>Classification Name
Classification Code
Regulatory Class
Regulation Number</td><td>Intervertebral body Fusion Device
MAX
Class II
21 CFR 888.3080</td></tr>
<tr><td>Predicate Device</td><td>
<table>
<tr><th>510K Number</th><th>Trade or Proprietary or Model Name</th><th>Manufacturer</th></tr>
<tr><td>K221844 (Primary)</td><td>TDM Lumbar Interbody Fusion Cage System</td><td>TDM Co. Ltd. Korea</td></tr>
<tr><td>K190563</td><td>4CIS® PEEK PLIF Cage,
4CIS® Pebble Beach PEEK PLIF Cage
4CIS® Torrey Pines PEEK TLIF Cage</td><td>Solco Biomedical Co., Ltd. Republic of Korea</td></tr>
<tr><td>K202498 (Reference)</td><td>4CIS SARA Spine System
4CIS VERTU Spine System</td><td>Solco Biomedical Company India Private limited</td></tr>
<tr><td>K162358</td><td>T-PAL Spacer System,
T-PAL Titanium Spacer System,
SYNFIXEvolution System</td><td>Synthes USA Products LLC</td></tr>
</table>
</td></tr>
<tr><td>Description of Device</td><td>The Intervertebral Body Fusion devices are designed for posterior lumbar interbody fusion (PLIF) & Transforaminal Lumbar Interbody Fusion (TLIF) techniques. It is a hollow</td></tr>
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	device intended for use as an intervertebral body fusion device in the lumbosacral region (L2-S1) of the spine. It is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation. The Spinal Fusion Cage System is single component devices used to restore height of disc and to facilitate lumbar intervertebral body fusion with maintaining physiological lordotic angulation of lumbar spine. To allow maximum preservation and ensure ample contact surfaces with bony endplate, a variety of shapes and sizes are available and each device made withh PEEK Polymer has tantalum (ASTM F560) markers for ease of visualization on radiographs. Vertical square teeth on the top and the bottom surface prevent subsidence of the cage into the vertebral body while they increase the anchoring and prevent slipping or expulsion. To make solid fusion of intervertebral body, hollow space in the implant allows autologous bone graft material to be filled. The implant has safety proven structure and material (Polyetheretherketone, ASTM F2026 & Titanium Ti6Al4V Eli ASTM F136) to promote biological synostosis and assures mechanical safety against load.
Indication for Use	The Spinal Fusion Cage System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Spinal Fusion Cage System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months of non-operative treatment.
Comparison of Technological Characteristics with the Predicate Devices	The subject device and all the predicates have the same or similar indications for use statements. 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. All they have similar basic design features and functions as well as those dimensions. The subject device and cited predicate devices are provided non-sterile for single use only. The subject device demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.
Performance Testing	Non-clinical testing was performed to demonstrate that the subject device is equivalent to the predicate device. The following testing was performed in accordance with the ASTM

	F2077-14 and F2267-04: - Static Axial Compression - Dynamic Axial Compression - Subsidence
Conclusion	The overall technology characteristics, material of construction, mechanical performance and design characteristics lead to the conclusion that subject device is substantially equivalent to legally marketed predicate devices for intended use,material composition, principles of operation, and design.