K121615

510(k) SUMMARY

AUG 15 2012

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information

Contact:	Seayoung Ahn 9700 Great Seneca Hwy, Sweet 302, Rockville, MD20850
Sponsor:	Solco Biomedical Co., Ltd. 34-6 Keumam-ri, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 451-852 Republic of Korea
Date Prepared:	March 14, 2006

Device Identification

Trade Name:	4CIS® VANE Spine System
Common Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Spondylolisthesis Spinal Fixation Device System(MNH) per 21 CFR § 888.3070, Spinal Pedicle Screw(MNI) per 21 CFR § 888.3070

Reason for this Submission

Poly axial and poly reduction screw sizes in diameter 8.0mm and length 20mm ~80 mm are added to the existing sizes.

Substantially Equivalent Predicate Legally Marketed Devices

The subject devices, 4CIS® VANE Spine System is substantially equivalent in function, design, composition, material and intended used to: Global Spinal Fixation System(K001668) and OPTIMA™, Spinal System(K031585), 4CIS® VANE Spine System(K101818)

Device Description

The 4CIS® VANE Spine System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, nuts, and a transverse (cross) linking mechanism.

The 4CIS® VANE Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. 4CIS® VANE Spine System

implant components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available. Specialized instruments are available for the application and removal of the 4CIS® VANE Spine System

Indications for Use

The 4CIS VANE Spine System is a posterior non-cervical pedicle screw system intended for use as an adjunct to fusion in patients with degenerative spondylolisthesis (Grade 3 and 4) with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis) of the lumbosacral spine vertebra and implants are removable after the attainment of a solid fusion. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

Performance Data

This is submitted as a Special 510k because these do not create any worst case at all in the testing (static and dynamic compression, static torsion testing per ASTM F1717) by considering biomechanical strength relationship.

Conclusion

Solco biomedical concludes that the changes to the system do not introduce any new risks and therefore, the system is Substantially Equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Solco Biomedical Company Limited
% Solco USA, Incorporated
Saeyoung Ahn
9700 Great Seneca Highway, Suite 302
Rockville, Maryland 20850

AUG 15 2012

Re: K121615
Trade/Device Name: 4CIS® VANE Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: July 19, 2012
Received: July 20, 2012

Dear Saeyoung Ahn:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121615

Device Name: 4CIS® VANE Spine System

Indications for Use:

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Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121615