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JUL 11 2005

510(k) SUMMARY

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

Submission Information

Contact:	Seayoung Ahn 7612 Barnum Road, Bethesda, MD 20817
Sponsor:	34-6 Keumam-ri, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 451-852 Republic of Korea
Date Prepared:	May 03, 2005

Device Identification

Trade Name:	SOLCO 4CIS® General Plate System
Common Name:	Bone Fixation Plate
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories(HRS), 21 CFR § 888.3030

Substantially Equivalent Predicate Legally Marketed Devices

The subject devices, SOLCO 4CIS® General Plate System, are substantially equivalent in function, design, composition, material and intended used to

1) Synthes Low Profile Reconstruction Plates (K042377) and
2) Smith & Nephew Bone Plate System (K993106).

Device Description

The SOLCO 4CIS® General Plate System consists of One-third Tubular plate, Small self compression plate, Reconstruction plate (Straight, Curved), Narrow self compression plate and Broad self compression plate. SOLCO 4CIS® General Plate System includes various sizes of implants to accommodate the individual requirements reflecting the patient anatomy. The components are manufactured from pure titanium material.

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Indications for Use

The SOLCO 4CIS® General Plate System is used for adult or pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femur, pelvis, metacarpals, metatarsals, humerus, ulna, radius, hand and middle foot bones.

Performance Data

Mechanical testing was conducted in accordance with ASTM F382 and demonstrates equivalence to the above predicate devices as listed in **APPENDIX 10**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Solco Biomedical Company, Ltd.
C/o Mr. Saeyoung Ahn
KLA MedTech Incorporated
7612 Barnum Road
Bethesda, Maryland 20817

Re: K051155
Trade/Device Name: SOLCO 4CIS® General Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: May 4, 2005
Received: May 9, 2005

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SOLCO 4CIS® General Plate System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K051155