AUG 7 2013

510(k) Summary

KATIA SYSTEM

July 22, 2013

Company:

Manufacturing Facility and Headquarters:
Shanghai Sanyou Medical Co, LTD
1988 Jiatang Road
Jiading District, Shanghai, 201807, China

Manufacturing Facility:
Shanghai Sanyou Medical Co, LTD
Rm 101/102/106/107
356 Renqing Rd, Building 3-1F,
Pudong New District, Shanghai 201201, China

Establishment Registration: Registration applied; Number not assigned

Primary Contact:

Kimberly Strohkirch
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Company Contact:

David Fan, VP, Marketing
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Fax: +86 21 38682915
david.fan@sanyou-medical.com

Trade Name: Katia System

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification: Class II

Regulation Number: 21 CFR 888.3060 (Spinal intervertebral body fixation orthosis)

Panel: 87- Orthopedic

Product Code: KWQ

Device Description:
The Katia System includes implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical fusion. The Katia system consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The components are made from titanium alloy.

Indications for Use:
The Katia System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fixation of the cervical spine (C2 – T1). The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (i.e. fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions, and/or 8) spinal stenosis.

Substantial Equivalence:
K081038 – Medtronic ATLANTIS® Anterior Cervical Plate System
K111132 - Genesys Spine Anterior Cervical Plate System
K031276 – Synthes Anterior Cervical Locking Plate (ACLP System)
K971883 – Synthes Small Stature Anterior Cervical Vertebrae Plate System

Performance Testing:
Testing was completed according to ASTM F1717-12 and Guidance for Industry and FDA Staff: Spinal System 510(k)s issued May 3, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 7, 2013

Shanghai Sanyou Medical Co, Ltd
% Memphis Regulatory Consulting
Ms. Kimberly Strohkirch
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K131512
Trade/Device Name: Katia System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 19, 2013
Received: June 20, 2013

Dear Ms. Strohkirch:

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 contact 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. 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 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 Erin I. Keith

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K131512

Device Name: Katia System

Indications for Use:

The Katia System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fixation of the cervical spine (C2 – T1). The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (i.e. fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions, and/or 8) spinal stenosis.

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

Anton E. Dmitriev, PhD
Division of Orthopedic Devices