DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 5, 2017

Shanghai Sanyou Medical Co, Ltd
% Christine Scifert
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K163366
Trade/Device Name: Shanghai Sanyou CARMEN Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, KWQ
Dated: September 5, 2017
Received: September 6, 2017

Dear Ms. Scifert:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163366

Device Name
Shanghai Sanyou CARMEN Cervical Fusion System

Indications for Use *(Describe)*
The Carmen plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of 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) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudoarthrosis, and/or 6) failed previous fusions.

Carmen anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyste formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non-operative treatment. The Carmen™ cage must be used with supplemental fixation. The Carmen™ cage is also required to be used with autogenous bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

When used together, the Carmen components can be used only to treat cervical disc disease.

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

Shanghai Sanyou CARMEN Cervical Fusion System

September 22, 2017

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
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356 Renqing Rd, Building 3-1F,
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Company Contact: David Fan, VP, Marketing
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Trade Name: Shanghai Sanyou CARMEN Cervical Fusion System

Common Name: Spinal Intervertebral Body Fixation Orthosis, Intervertebal Body Fusion Device

Classification: Class II

Regulation Number: 21 CFR 888.3060 (Spinal Intervertebral Body Fixation Orthosis)
21 CFR 888.3080 (Intervertebal Body Fusion Device)

Panel: 87- Orthopedic

Product Code: KWQ, ODP

Primary Predicate

Device: K142450 – Medtronic Sofamor Danek, DIVERGENCE™ Anterior Cervical Fusion System

Additional Predicate

Devices: K100214 – Medtronic Sofamor Danek CORNERSTONE® PSR Spinal System
K131512 – Shanghai Sanyou, Katia Cervical Plate

Device Description:

Shanghai Sanyou Carmen™ Cervical Fusion System includes cervical plates and screws and interbody cages to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The interbody device is available in 2 widths (12 mm and 14 mm) and 4 heights (4, 5, 6 and 7 mm) and is composed of PEEK. The interbody device is offered with only one lordosis angle; each size is available with 7° lordosis. The plate is available in small or large with an integrated locking screw. The self-tapping screw is available in 3.5 or 4.0 mm diameter screws either 13 mm, 15 mm or 17 mm in length.

Indications for Use:

The Carmen™ plate and bone screw components are intended for anterior interbody screw fixation from C2-TI. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of 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) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), *5)* pseudoarthrosis, and/or 6) failed previous fusions.

Carmen™ anterior cervical cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of non-operative treatment. The Carmen™ cage must be used with supplemental fixation. The Carmen™ cage is also required to be used with autogenous bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

When used together, the Carmen™ components can be used only to treat cervical disc disease.

Performance Testing:
Static and dynamic axial compression bending, static torsion, static shear compression bending and subsidence testing were completed for the Shanghai Sanyou PEEK Cage System according the ASTM F2077-14, ASTM F2067-04, and Guidance for Industry and FDA Staff: Spinal System 510(k)s issued May 3, 2004. Plate dynamic compression testing was conduct according to ASTM F1717-15. Performance testing demonstrates that the subject device meets or exceeds performance of predicate devices demonstrating that the subject devices are substantially equivalent to the predicate devices.

Comparison of Technology:

The subject and primary predicate device (DIVERGENCE Anterior Cervical Fusion System) include a titanium alloy cervical plate component that mates with a PEEK interbody device. Additionally, the indications for use is the same for the subject device as the predicate device. The primary difference between the subject and predicate devices is the size range of plates and locking screws. The subject plate components range include a 16.5 mm and 18.5 mm plate with 13, 14 and 17 mm length locking screws. The predicate plate components have a larger range of sizes included 15.5-20.5 mm plates and 9-17 mm locking screws. Additionally, there are geometry differences between the subject and predicate devices. Mechanical testing demonstrates that the subject device is substantially equivalent to the predicate devices.

Substantial Equivalence:
The subject systems components are similar in sizes, materials and geometry to the predicate components. The subject components have the same indications as the predicate components. The difference in the subject and predicate devices do not rendered the system not substantially equivalent.

(Primary Predicate) K142450 – Medtronic Sofamor Danek, DIVERGENCE™ Anterior Cervical Fusion System
K100214 – Medtronic Sofamor Danek CORNERSTONE® PSR Spinal System
K131512 – Shanghai Sanyou, Katia Cervical Plate