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

Re: K163422
Trade/Device Name: Shanghai Sanyou PEEK Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: August 25, 2017
Received: August 30, 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,

Mark N. Melkerson -S

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

Enclosure
Device Name
Shanghai Sanyou PEEK Cage System

Indications for Use

Indications for Use (Describe)
The Halis™ Lumbar Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have had six months of non-operative treatment prior to surgery. The Halis™ Lumbar Cage System is intended to be used with autogenous bone graft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are intended to be used with supplemental fixation. The devices may be implanted through several surgical approaches: transforaminal, posterior, oblique, and direct lateral. When implanted through the direct lateral approach, the Halis™ Lumbar Cage System is only indicated for use in levels L2-L5.

The Caro™ Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to surgery. Caro™ Cervical Cage System implants are placed via an anterior approach and is to be used with autogenous bone graft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are intended to be used with supplemental fixation.

The Lydia™ Anterior Lumbar Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach. The devices are intended to be used with supplemental fixation. This device is not intended for cervical spine use.

The Dica™ Direction Changeable Lumbar Cage System is indicated for interbody fusion with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have six months of non-operative treatment prior to surgery. The devices are intended to be used with supplemental fixation.

Type of Use (Select one or both, as applicable)

- [x] 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 PEEK Cage System  
September 8, 2017

**Company:** 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

**Primary Contact:** Christine Scifert  
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**Company Contact:** David Fan, VP, Marketing  
Phone: +86 21 58389980  
Fax: +86 21 38682915  
david.fan@sanyou-medical.com

**Trade Name:** Shanghai Sanyou PEEK Cage System

**Common Name:** Intervertebral Body Fusion Device with Bone Graft, Cervical  
Intervertebral Body Fusion Device with Bone Graft, Lumbar

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3080 (Intervertebral Body Fusion Device)

**Panel:** 87- Orthopedic

**Product Code:** ODP, MAX

**Primary Predicate Device:** K132897 – Medtronic Clydesdale® Spinal System

**Additional Predicate Devices:**  
K072791 – Depuy Synthes Spine, OPAL Spacer  
K094025 – Medtronic Sofamor Danek, CRESCENT™ Spinal System  
K151128 – Medtronic Sofamor Danek, CAPSTONE® Spinal System  
K153373 – Medtronic Sofamor Danek, CORNERSTONE® PSR Cervical Fusion System
**Device Description:**

The Shanghai Sanyou PEEK Cage System consists of four different models of fusion devices:
- Caro™ Cervical Cage System
- Halis™ Lumbar Cage System
- Lydia™ Anterior Lumbar Fusion System
- Dica™ Direction Changeable Lumbar Cage System

All components are made of polyetheretherketone (PEEK). All fusion devices are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical or lumbar spine. These Fusion Devices consist of PEEK cages of various heights, widths and lengths, which can be inserted between two lumbar or cervical vertebral bodies to give support and correction during intervertebral body fusion surgeries. All components have serrations on the superior and inferior surfaces of the implant to aid in fixation. The hollow geometry of the implants allows them to be packed with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Radiopaque Markers manufactured from unalloyed tantalum have been embedded within the implant to allow for visualization in radiographic images. Associated instruments are available to facilitate the implantation of device.

Several additional predicates and reference devices are identified and are used to support the substantial equivalence of the individual components of the Shanghai Sanyou PEEK Cage System as described in Table 1 below.

**Table 1. Predicate and Reference Devices**

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Predicate Usage</th>
<th>Subject Device Supported</th>
<th>Rationale for Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>K132897, Clydesdale Spinal System</td>
<td>Lumbar</td>
<td>Halis™ Lumbar Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
<tr>
<td>K072791, OPAL Spacer</td>
<td>Lumbar</td>
<td>Halis™ Lumbar Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
<tr>
<td>K094025, Crescent Spinal System</td>
<td>Lumbar</td>
<td>Dica™ Direction Changeable Lumbar Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
<tr>
<td>K151128, Capstone Spinal System</td>
<td>Lumbar</td>
<td>Halis™ Lumbar Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
<tr>
<td>K153373, Cornerstone Spinal System</td>
<td>Cervical</td>
<td>Caro™ Cervical Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
</tbody>
</table>

**Reference Devices**

<table>
<thead>
<tr>
<th>Reference Device</th>
<th>Reference Usage</th>
<th>Subject Device Supported</th>
<th>Rationale for Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>K150765, ROI-C Fusion System</td>
<td>Cervical</td>
<td>Caro™ Cervical Cage System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
<tr>
<td>K121982, Sovereign Spinal System</td>
<td>Lumbar</td>
<td>Lydia™ Anterior Lumbar Fusion System</td>
<td>Equivalent size range, anatomic usage, and implantation approach</td>
</tr>
</tbody>
</table>
Indications for Use:
The Halis™ Lumbar Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have had six months of non-operative treatment prior to surgery. The Halis™ Lumbar Cage System is intended to be used with autogenous bone graft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are intended to be used with supplemental fixation. The devices may be implanted through several surgical approaches: transfemoral, posterior, oblique, and direct lateral. When implanted through the direct lateral approach, the Halis™ Lumbar Cage System is only indicated for use in levels L2-L5.

The Caro™ Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to surgery. Caro™ Cervical Cage System implants are placed via an anterior approach and is to be used with autogenous bone graft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are intended to be used with supplemental fixation.

The Lydia™ Anterior Lumbar Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach. The devices are intended to be used with supplemental fixation. This device is not intended for cervical spine use.

The Dica™ Direction Changeable Lumbar Cage System is indicated for interbody fusion with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have six months of non-operative treatment prior to surgery. The devices are intended to be used with supplemental fixation.

Performance Testing:
Static and dynamic axial compression, static shear compression, static torsion and were completed for the Shanghai Sanyou PEEK Cage System according the ASTM F2077-14 and Guidance for Industry and FDA Staff: Spinal System 510(k)s issued May 3, 2004. Additionally, subsidence testing was completed according to ASTM F2267-04. 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.
**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 subject devices are substantially equivalent to the predicate devices.

- K132897 – Medtronic Clydesdale® Spinal System
- K072791 – Depuy Synthes Spine, OPAL Spacer
- K094025 – Medtronic Sofamor Danek, CRESCENT™ Spinal System
- K151128 – Medtronic Sofamor Danek, CAPSTONE® Spinal System
- K153373 – Medtronic Sofamor Danek, CORNERSTONE® PSR Cervical Fusion System