December 12, 2023

Shanghai Sanyou Medical Co, LTD
℅ Christine Scifert
Partner
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, CO 80112

Re: K230872
Trade/Device Name: Halis™ Lumbar Cage System, Lydia™ Anterior Lumbar Fusion System, Dica™ Direction Changeable Lumbar Cage System, KEYSTONE Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 16, 2023
Received: November 16, 2023

Dear Christine 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230872

Device Name
Dica Direction Changeable Lumbar Cage System

Indications for Use *(Describe)*
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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Halis Lumbar Cage System

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 S 1 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. .

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
KEYSTONE Cage System

Indications for Use *(Describe)*

The KEYSTONE Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation. 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. Additionally, the KEYSTONE Cage System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. Patients should have had six months of non-operative treatment prior to surgery. The KEYSTONE Cage System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. When used for these indications, the KEYSTONE PEEK Cage System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These implants may be implanted via a minimally invasive lateral approach.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Lydia Anterior Lumbar Spinal System

Indications for Use *(Describe)*
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.

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)

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K230872

510(k) Summary

Metal Additive Manufacturing Interbody Fusion Cages

Company:	Manufacturing Facility and Headquarters: Shanghai Sanyou Medical Co, LTD 385 Huirong Road, Jiading District, Shanghai 201815 Phone: 021-58389980 Manufacturing Facility: Shanghai Sanyou Medical Co, LTD 385 Huirong Road, Jiading District, Shanghai 201815 Phone: 021-58389980
Company Contact:	David Fan VP Marketing david.fan@sanyou-medical.com Phone: +86 21 58389980 Fax: +86 21 38682915
Official Correspondent:	Christine Scifert – MRC Global, LLC Christine.scifert@askmrcglobal.com 901-831-8053
Trade Names:	Halis™ Lumbar Cage System Lydia™ Anterior Lumbar Fusion System Dica™ Direction Changeable Lumbar Cage System KEYSTONE Cage System
Common Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II
Regulation Number:	21 CFR 888.3080 (Intervertebral body fusion device)
Panel:	Orthopedic
Product Code:	MAX

Device Description:

The Shanghai Sanyou Cage System (K163422) 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 – that are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. These previously cleared 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 interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autograft and/or allogenic bone graft material.

Additionally, the KEYSTONE Cage System (K211689) consists of lumbar intervertebral body fusion devices (IBDs), provided in parallel or lordotic options with varying footprints to accommodate patient anatomy. The subject KEYSTONE cages (IBDs) contain serrations across both superior and inferior surfaces to allow the implant to grip the superior and inferior end plates to provide expulsion resistance. These previously devices are manufactured from medical grade polyetheretherketone (PEEK) material per ASTM F2026 and contain radiopaque tantalum pin markers per ASTM F560 for imaging purposes. Implants are to be inserted via a crenel-lateral (CLIF) approach.

The subject submission seeks to add additively manufactured versions of all families in the Shanghai Sanyou Cage System, except the Caro™ Cervical Cage System, along with the KEYSTONE cages. The subject cages are similar to the previously cleared devices above with the exception that they are additively manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F3001 and the finished product conforms to ASTM F2924. The subject additively manufactured implants (also referred to as "metal additive manufacturing cages" or "MAM") are provided sterile via gamma irradiation. The additively manufactured cages will also be offered in an extended size range.

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 S 1 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 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.

The KEYSTONE Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation. 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. Additionally, the KEYSTONE Cage System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. Patients should have had six months of non-operative treatment prior to surgery. The KEYSTONE Cage System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. When used for these indications, the KEYSTONE PEEK Cage System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These implants may be implanted via a minimally invasive lateral approach.

Substantial Equivalence:

The subject Shanghai Sanyou Metal Additive Manufacturing Interbody Fusion Cages is substantially equivalent to the following predicate devices:

Primary Predicate:

- EIT Cellular Titanium® Cervical Cage; EIT Cellular Titanium® ALIF Cage; EIT Cellular Titanium® TLIF Cage; EIT Cellular Titanium® LLIF Cage; EIT Cellular Titanium® T/PLIF Cage – K201605

Secondary Predicates:

- Shanghai Sanyou PEEK Cage System: K163422
- Shanghai Sanyou KEYSTONE PEEK Cage System: K211689

There are differences between the subject Shanghai Sanyou Metal Additive Manufacturing Interbody Fusion Cages and the predicates including an expanded size range. The Indications for Use, Materials, and Geometry for predicate devices are similar to those of the subject device. The subject device is provided sterile, similar to the primary predicate device. Testing shows that the subject Metal Additive Manufacturing Interbody Fusion Cages perform equivalent to or better than the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Bench performance testing was performed on the subject Metal Additive Manufacturing Interbody Fusion Cages including static and dynamic axial compression and static shear compression per ASTM F2077-14. Subsidence testing was also performed per ASTM F2267-04.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.