September 21, 2021

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

Re: K211689
Trade/Device Name: KEYSTONE PEEK Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 10, 2021
Received: August 11, 2021

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

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)*
K211689

Device Name
KEYSTONE PEEK Cage System

Indications for Use *(Describe)*
The KEYSTONE PEEK 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 toS1 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 PEEK 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 PEEK 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
KEYSTONE PEEK Cage System
17 September 2021

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 Name:	KEYSTONE PEEK 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:
KEYSTONE PEEK Cage System 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. Subject devices are manufactured from medical grade polyetheretherketone (PEEK) material per ASTM F2026 and contain radiopaque tantalum pin markers per ASTM F560 for imaging purposes. The subject implants are to be inserted via a crenel-lateral (CLIF) approach.

Indications for Use:
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Substantial Equivalence:
The subject KEYSTONE PEEK Cage System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Medtronic, CLYDESDALE® Spinal System: K083026, K132897, K151128

Secondary Predicates:

- Shanghai Sanyou PEEK Cage System Halis Cage: K163422

There are insignificant differences between the subject KEYSTONE PEEK Cage System and the predicates. The Indications for Use, Materials, and Geometry for predicate devices are all inclusive of the subject device. Testing shows that the subject KEYSTONE PEEK Cage System performs 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 KEYSTONE PEEK Cage System implants including dynamic axial compression per ASTM F2077-14.

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.