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

August 16, 2021

Re: K212066
Trade/Device Name: Adena-Zina System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 25, 2021
Received: July 2, 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

Colin O'Neill, M.B.E.
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)*
K212066

Device Name
Adena-Zina System

Indications for Use *(Describe)*
The Adena-Zina System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Adena-Zina System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

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
Adena-Zina System
13 August 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:	Adena-Zina System
Common Name:	Thoracolumbosacral pedicle screw system
Classification:	Class II
Regulation Number:	21 CFR 888.3070 (Thoracolumbosacral pedicle screw system)
Panel:	Orthopedic
Product Code:	NKB
Primary Predicate:	Shanghai Sanyou Medical Co, LTD, Adena-Zina System (K152781)
Additional Predicate:	Globus Medical Inc., CREO™ Stabilization System (K124058)

Device Description:
The Adena-Zina System consists of a variety of shapes and sizes of screws, 5.5mm and 6.35mm rods, and other connecting components that can be rigidly locked in a variety of configurations, with each construct being tailor-made for the individual case. Fixation is provided via a posterior approach. All implant components are made from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F-136/ISO 5832-3 or cobalt chrome alloy per ASTM F1537-11/ISO 5832-12.

The purpose of this submission is to add the Duetto dual headed Screws and connectors, along with associated set screws to the Adena-Zina Spinal System.

Indications for Use:
The Adena-Zina System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

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Substantial Equivalence:
The Adena-Zina System is substantially equivalent to the predicate devices in regards to the indications for use, materials, and geometry and does not raise new questions about safety and effectiveness.

Performance Testing:
Bench performance testing was performed on the subject Duetto Screws of the Adena-Zina System including static compression, static torsion, and dynamic axial compression per ASTM F1717-18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

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.