



October 10, 2023

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

Re: K230961

Trade/Device Name: Zeus Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 11, 2023
Received: September 11, 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,

Colin
O'Neill -S 

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

Indications for Use

510(k) Number (if known)
K230961

Device Name
Zeus Spinal System

Indications for Use (Describe)

The Zeus Spinal 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 Zeus Spinal 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
Zeus Spinal System
4 April 2023

Company: Manufacturing Facility and Headquarters:
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901-831-8053

Trade Name: Zeus Spinal 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

Device Description:

The Zeus Spinal System is a modification of the previously cleared Adena-Zina Spinal System which consists of a variety of shapes and sizes of screws and Ø5.5mm and Ø6.35mm rods 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. The components are made from titanium alloy or cobalt chrome alloy. Components of the system include the originally cleared (K152781) straight and pre-bent rods, fixed and fixed angle reduction screws, multi-axial and multi-axial reduction screws, T-links, domino connectors, sacro-iliac connectors, as well as the Duetto dual headed screws and connectors, along with associated set screws (K212066)

The subject submission seeks to add new Ø5.5mm pre-bend rods, single head and dual head polyaxial (multi-axial) screws, dual head reduction screws, polyaxial reduction screws (fixed polyaxial fixed screws, dual head monoaxial (fixed) screws, cannulated reduction screws (multi-axial and monoaxial), coronal and sagittal uniplanar screws, preferable angle screws, module screws, iliac screws, monoaxial Screw, associated set screws, connector and Ø5.5mm crosslinks, as well as additional sizes of existing components and cobalt chrome tulips for associated screws.

Indications for Use:

The Zeus Spinal 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 Zeus Spinal 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.

Substantial Equivalence:

The subject Zeus Spinal System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Shanghai Sanyou Adena-Zina System – K152781

Secondary Predicates:

- Shanghai Sanyou Adena-Zina System – K212066
- Medtronic CD Horizon Spinal System– K201407
- DePuy Spine, Inc. EXPEDIUM® Spine System – K102249

There are insignificant differences between the subject Zeus Spinal System and the predicate devices. The Indications for Use and Materials for predicate devices are all inclusive of the subject device, with the subject device materials and indications being identical to the primary predicate Adena-Zina System (K152781). While Zeus Spinal System does include size offering/geometry outside of the predicate offerings, performance bench testing had been performed and shows that the subject Zeus Spinal System performs equivalent to or better than the primary predicate device. 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 Zeus Spinal System implants including static axial compression, dynamic axial compression, and static torsion per ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*. Additionally, screw dissociation testing was performed per ASTM F1798 *Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanism and Subassemblies Used in Spinal Arthrodesis Implants*

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.