



Food and Drug Administration
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Shanghai Sanyou Medical Company, Limited
% Kimberly Strohkirch, MSE
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

February 12, 2016

Re: K152781
Trade/Device Name: Adena-Zina System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: January 25, 2016
Received: January 27, 2016

Dear Ms. Strohkirch:

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 Parts 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 yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152781

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

January 25, 2016

Company: Manufacturing Facility and Headquarters:
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Trade Name: Adena-Zina System

Common Name: Pedicle Screw Spinal System

Classification: Class III

Regulation Number: 21 CFR 888.3070 (Orthosis, Spondylolisthesis Spinal Fixation; Orthosis, Spinal Pedicle Fixation)

Panel: 87- Orthopedic

Product Code: NKB, MNH, MNI

Predicate Devices: K123809 – Medtronic CD Horizon Spinal System
(primary predicate device)

Additional predicate devices:

K013962 – Medtronic EQUATION™ Fixation System

K122332 – Captiva Spine TowerLOX Pedicle Screw System

Device Description:

The Adena-Zina System consists of a variety of a variety of shapes and sizes of screws and 5.5 and 6.35 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 straight and pre-bent rods, fixed and fixed angle reduction screws, multi-axial and multi-axial reduction screws, T-links, domino connectors, and sacro-iliac connectors.

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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Performance Testing:

Static compression bending, static torsion, and fatigue compression bending were completed for the Adena-Zina System in accordance with ASTM F1717-12 and Guidance for Industry and FDA Staff: Spinal System 510(k)s issued May 3, 2004. In addition, the connectors underwent axial grip testing in accordance with ASTM F1798-13. This performance testing demonstrated that the subject device meets or exceeds performance of the predicate device.

Substantial Equivalence:

The Adena-Zina System is substantially equivalent to the cleared predicate device, the Medtronic CD Horizon Spinal System (K123809), because it has similar indications for use, is composed of the same materials, and has similar technological characteristics. In addition, the Adena-Zina system meets or exceeds the performance of the predicate device in bench tests.