



May 6, 2024

Implanet  
% Christine Scifert  
Regulatory Consultant  
MRC Global  
9085 East Mineral Circle, Suite 110  
Centennial, Colorado 80112

Re: K240392

Trade/Device Name: JAZZ Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Thoracolumbosacral Pedicle Screw System  
Regulatory Class: Class II  
Product Code: NKB  
Dated: February 5, 2024  
Received: February 8, 2024

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Eileen  
Cadel -S**  Digitally signed  
by Eileen Cadel -  
S  
Date: 2024.05.06  
12:45:28 -04'00'

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

## Indications for Use

510(k) Number (if known)  
K240392

Device Name  
JAZZ Spinal System

### Indications for Use (Describe)

The JAZZ 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 JAZZ 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**  
JAZZ Spinal System  
May 6, 2024

**Company:** Implanet  
Technopole Bordeaux Montesquieu  
Allee F.Magendie  
Martillac Nouvelle-Aquitaine, FR 33650

**Primary Contact:** Christine Scifert – Partner  
MRC Global  
9085 E. Mineral Cir., Suite 110  
Centennial, CO 80112  
Phone: (901) 831-8053  
Email: christine.scifert@AskMRCGlobal.com

**Company/Secondary Contact:** Régis Le Couëdic  
VP R&D-RA  
Implanet  
Phone: + 33 557 995 660  
[reglementaire@implanet.com](mailto:reglementaire@implanet.com)

**Trade Name:** JAZZ Spinal System

**Common Name:** Thoracolumbosacral pedicle screw system

**Classification:** Class II

**Regulation:** 21 CFR 888.3070 (Thoracolumbosacral pedicle screw system)

**Panel:** Orthopedic

**Product Code:** NKB

## **Device Description:**

The JAZZ Spinal System consists of a variety of shapes and sizes of screws and 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, monoaxial and polyaxial screws (cannulated and non-cannulated), reduction screws, domino connectors, lateral connectors, crosslinks, dual headed screws and connectors, transverse and sagittal uniplanar screws, favored angle screws, modular screws, S2AI screws, along with associated set screws and class I instrumentation.

## Indications for Use:

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

Primary Predicate:

- Shanghai Sanyou Zeus System –K230961

Additional Predicates:

- Shanghai Sanyou Adena-Zina System – K152781
- Implanet ISS-JAZZ Screw System and JAZZ CAPP – K182771
- IMPLANET Spine System (ISS) – K143731

The subject device is substantially equivalent to the predicate devices with respect to intended use, function, design, materials, and mechanical performance.

## Performance Testing:

Bench performance testing was performed including static axial compression, dynamic axial compression, and static torsion per ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*; Static Axial grip, Static Nominal Dissociation, and Static Maximum Angle Dissociation per ASTM F1798 *Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*.

## Conclusion:

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