March 12, 2019

Implanet, S.A.
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K182771
Trade/Device Name: ISS-JAZZ Screw System and JAZZ CAP SP
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, OWI
Dated: February 6, 2019
Received: February 6, 2019

Dear Ms. Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 6/30/2020
See PRA Statement on last page

510(k) Number *(if known)*
K182771

Device Name

ISS-JAZZ Screw System and JAZZ CAP SP

Indications for Use *(Describe)*

The ISS-JAZZ Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The ISS-JAZZ Screw System is intended for posterior, non-cervical pedicle and non-pedicle fixation 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, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis, or revision of a failed fusion attempt.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ISS-JAZZ Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The JAZZ systems (including the JAZZ Claw Connector) are temporary implants to be used in orthopedic surgery. The JAZZ systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ Systems may also be used in conjunction with other medical implants made of titanium alloy or Cobalt-chromium-molybdenum alloy whenever "wiring" may help secure the attachment of other implants.

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

ISS-JAZZ Screw System and JAZZ CAP SP

Submitter

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Contact Person: Fabienne Larquey Cadiere

Date Prepared: February 6, 2019

Name of Device: ISS-JAZZ Screw System and JAZZ CAP SP

Classification Name: Thoracocolumbar pedicle screw system

Regulatory Class: 21 C.F.R. 888.3070; 21 CFR 888.3010

Product Code: NKB, OWI

Predicate and Reference Devices

- Implanet Spine System (ISS) (K143731) (Primary predicate for ISS-JAZZ Screw System)
- JAZZ System (K171881) (Reference device for JAZZ CAP SP)
- JAZZ Lock (K153348) (Reference device for JAZZ CAP SP)

Device Description

The JAZZ CAP SP is composed of three components, the Cap SP, the Base SP, and the Insert Lock. The head shape ISS pedicle screws is modified from the current tulip shape to a cylindrical shape to match the Cap SP, resulting in the JAZZ Screw. The ISS-JAZZ Screw System is composed of monoaxial and polyaxial screws and straight and pre bent rods. The JAZZ CAP SP is added to the proximal end of the JAZZ Screw and provides for an alternate method to attach the JAZZ Band and JAZZ Passer Band to skeletal structures as compared to the current method of using a JAZZ Connector (K171881).

Intended Use / Indications for Use

The ISS-JAZZ Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The ISS-JAZZ Screw System is intended for posterior, non-cervical pedicle and non-pedicle fixation 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,

spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis, or revision of a failed fusion attempt.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ISS-JAZZ Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The JAZZ systems (including the JAZZ Claw Connector) are temporary implants to be used in orthopedic surgery. The JAZZ systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ Systems may also be used in conjunction with other medical implants made of titanium alloy or Cobalt-chromium-molybdenum alloy whenever "wiring" may help secure the attachment of other implants.

Comparison of Technological Characteristics

The ISS-JAZZ Screw System and the JAZZ CAP SP System provide an alternate way to allow for braid attachment to the spine. Currently, like any pedicle screw system, the ISS can be combined with the JAZZ System that contains JAZZ Connectors that attach to the rods. These connectors also contain the JAZZ Band or JAZZ Passer Band, which is then attached to the spine. The ISS-JAZZ Screw System and the JAZZ CAP SP System subject of this submission provide a more efficient, lower profile method of adding the braid attachment by modifying the pedicle screw to directly attach to the JAZZ Passer Band to the JAZZ CAP SP on the proximal end of the screw. The locking mechanism used for the braid component in the JAZZ CAP SP is identical to that already cleared in the JAZZ Lock (K153348).

In order to be compatible with the JAZZ CAP SP, the head of the ISS screws have been modified from tulip shaped to cylindrical shaped, creating the JAZZ Pedicle Screw. Both systems have identical pedicle screw and rods diameters and lengths. The same materials and manufacturing methods as have been previously cleared are used to manufacture the ISS-JAZZ Screw System and JAZZ CAP SP. Similarly, the same sterilization methods are used.

Performance Data

Dynamic compression testing per ASTM F1717 has been performed on the worst-case construct to establish equivalence to the predicate. Detailed rationales were provided to demonstrate why the device did not constitute a new worst-case in terms of sterilization,

cleaning and biocompatibility. Additional static axial load testing was conducted to characterize the maximum load placed by the Band on the JAZZ CAP SP to cause a displacement on the JAZZ Screw. These test results demonstrated that the proposed device has substantially equivalent performance as the predicate device.

Conclusions

The ISS-JAZZ Screw System and JAZZ CAP SP are as safe and effective as the predicate devices. The subject devices have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate and reference devices. The minor differences in indications do not alter the intended therapeutic use of the devices and do not affect their safety and effectiveness when used as labeled. In addition, the minor technological differences between the subject devices and their predicate and reference devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ISS-JAZZ Screw System and JAZZ CAP SP are as safe and effective as the predicate and reference devices. Thus, the ISS-JAZZ Screw System and JAZZ CAP SP are substantially equivalent.