August 2, 2019

Implanet, S.A.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1845 Market Street, Suite 230
Philadelphia, Pennsylvania 19103

Re: K191217
Trade/Device Name: JAZZ PF
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: May 6, 2019
Received: May 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/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,

Ronald P. Jean, Ph.D.
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: 6/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K191217

Device Name

JAZZ PF

Indications for Use *(Describe)*

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

JAZZ PF

Submitter

Implanet, S.A.
Technopole Bordeaux Montesquieu
Allée Francois Magendi
33650 Martillac
Phone: (+33) 557 995 555
Facsimile: (+33) 557 995 700

Contact Person: Fabienne Larquey Cadiere

Date Prepared: August 1, 2019

Name of Device: JAZZ PF

Classification Name: Bone fixation cerclage

Regulatory Class: 21 CFR 888.3010

Product Code: OWI

Primary Predicate and Reference Devices

- Primary Predicate: NuVasive VersaTie System (K173117)
- Additional Predicate: ISS-JAZZ Screw System and JAZZ CAP SP (K182771)

Device Description

JAZZ PF enables the passing of a JAZZ braid around or through the upper spinous process. The main difference with the JAZZ regular connector is that in the subject device the braid is locked horizontally, that is, along the spine axis, instead of vertically. On each side of the instrumented levels, a JAZZ PF connector is implanted on the union rod below the upper pedicle screw. A JAZZ braid is passed and locked through a 1st connector, above or through the spinous process and back through the second connector on the other side. The slack that can exist in the band is removed using the JAZZ PF Band Reducer (Enrouleur Instrument) without applying any tension in the band and the 2nd connector is locked. By doing so, flexion is controlled which helps in the primary stabilization of the levels where fusion has to be achieved.

Intended Use / Indications for Use

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 JAZZ PF is an additional component of the JAZZ System that was cleared under K182771. The proposed device uses similar technological characteristics of braided bands and clamps as the primary predicate, VersaTie System, to stabilize the spine. Specifically, the subject device, similar to the NuVasive VersaTie System, is secured around posterior vertebral structures such as the lamina, facet, transverse processes, and spinous process from T1-L5. The system is comprised of braided bands and clamps designed to attach to c rods.

The following table compares the technological characteristics of the JAZZ PF with the predicate devices:

	Subject Device JAZZ PF	**Primary Predicate Device NuVasive VersaTie System**	**Additional Predicate Device JAZZ System**	**Comparison**
510(k)	Subject	K173117	K182771	
Braid Connector	Yes	Yes	Yes	Same
Braid	Yes	Yes	Yes	Same
Materials	Ti alloy, polyester	Ti or CoCr alloy, polyester	Ti alloy, polyester	Similar biocompatible materials
Connection Method to Spine	Braid, rods and pedicle screws	Braid, rod and pedicle screws	Braid, rod, and pedicle screws	Same
Braid Locking Method	As internal screw is tightened, the connector clamps the braid	As internal screw is tightened, the connector clamps the braid	As internal screw is tightened, the connector clamps the braid	Same
Sizes	5.5-6mm	5-6mm	5.5-6mm	Similar range of sizes

Performance Data

Dynamic compression testing of the subject device was performed on a lumbar construct mounted on a test block and attached to the fixed test machine jaw. The JAZZ PF constructs passed 5 million cycles at a load of 600N. Detailed rationales were provided to demonstrate why the device did not constitute a new worst-case in terms of sterilization, cleaning and biocompatibility.

Conclusions

The JAZZ PF is substantially equivalent to predicate devices. The subject devices have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. In addition, the minor technological differences between the subject device and the predicate devices raise no new issues of safety or effectiveness. In particular, the JAZZ PF provides an alternate way to allow for the braid attachment to the spine, similar to how the ISS-JAZZ Screw System and the JAZZ CAP SP System (cleared under K182771) provides an additional method for stabilization. In particular, the NuVasive VersaTie System (K173117) uses similar technological characteristics of braided bands and clamps in the same manner as the subject device around the same intended anatomical location. Performance data demonstrate that the JAZZ PF is as safe and effective as the predicate devices. Thus, the JAZZ PF is substantially equivalent to the predicate devices.