DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 9, 2017

Implanet, S.A.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, Pennsylvania 19103

Re: K170730
Trade/Device Name: JAZZ System, including JAZZ Band
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 3, 2017
Received: April 3, 2017

Dear Janice 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. 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); 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,

Mark N. Melkerson -S

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: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*
K170730

Device Name
JAZZ System, including JAZZ Band

Indications for Use *(Describe)*

JAZZ is a temporary implant to be used in orthopedic surgery. The JAZZ System is 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 spinaldeformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ System 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**
**Implanet's JAZZ System. including JAZZ Band**
**K170730**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:**

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Contact Person: Regis Le Couedic, Director of Quality and Regulatory Affairs; Chief Technology Officer

Date Prepared: June 8, 2017

**Application Correspondent:**

Janice M. Hogan
1835 Market Street, 29th Floor
Philadelphia, PA 19103
Phone: (267) 675-4611

**Name of Device:**

JAZZ System, including JAZZ Band

**Common or Usual Name:**

Bone, Fixation, Cerclage, Sublaminar

**Classification Name:**

Bone, Fixation, Cerclage

**Primary Product Code**

OWI

**Regulation Number**

21 CFR § 888.3010

**Device Class**

Class II

**Predicate Devices**

Implanet's JAZZ System (K151740) (primary)

Implanet's JAZZ Systems (K162764) (additional)

Implanet's JAZZ Lock (K153348) (additional)

**Device Description**

The JAZZ Systems consists of the following components: JAZZ Connector, JAZZ Claw Connector, JAZZ Claw hooks, JAZZ Lock Connector, various rods, and JAZZ Braid (a.k.a. Band) with buckle. The JAZZ Band is inserted into various JAZZ connectors and is used to attach them to the spine.

**Intended Use/Indications for Use**

JAZZ is a temporary implant to be used in orthopedic surgery. The JAZZ System is 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 spinaldeformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ System 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.

**Purpose of 510(k)**

The purpose of this 510(k) is to modify the Jazz Band component of the JAZZ Systems. Minor changes are being made to the ultrasonic welding of the braid and the design of the metal buckle used to tighten the braid.

**Performance Data**

These changes were assessed per ISO 10993 and static tensile testing to show equivalent biocompatibility and mechanical performance to the predicate.

**Conclusions**

The modified JAZZ Band is as safe and effective as the predicate JAZZ Braid. The JAZZ Band has the same intended uses and indications, as well as similar technological characteristics and principles of operation as its predicate device. In addition, the minor technological differences between the JAZZ Band and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the modified JAZZ

Band is as safe and effective as the predicate JAZZ Braid. Thus, the JAZZ Band is substantially equivalent.