DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 18, 2016

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

Re: K160226
Trade/Device Name: JAZZ CLAW System (hooks and rods) and JAZZ CLAW connector
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, OWI
Dated: April 11, 2016
Received: April 11, 2016

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. 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" (21CFR 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

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)*

K160226

Device Name

JAZZ CLAW System (hooks and rods)

Indications for Use *(Describe)*

The Jazz Claw System (hooks and rods) 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 Jazz Claw System (hooks and rods) is intended for posterior 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 (fracture or dislocation);
- spinal stenosis;
- spinal deformities (scoliosis, kyphosis and/or lordlosis)
- tumor;
- pseudarthrosis; and
- revision of a failed fusion attempt.

The Jazz Claw System (hooks and rods) is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft.

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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# 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)*

K160226

Device Name

JAZZ CLAW connector

Indications for Use *(Describe)*

The JAZZ CLAW connector consists of temporary implants to be used in orthopedic surgery. The JAZZ CLAW connector 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 spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ CLAW connector 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.**

**510(k) SUMMARY**

**Implanet, S.A.'s JAZZ CLAW System (hooks and rods) and JAZZ CLAW connector**

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

Implanet S.A.
Technopole Bordeaux Montesquieu
Allée François Magendie
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France

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

Date Prepared: May 17, 2016

**Name of Device**

1. JAZZ CLAW connector
2. JAZZ CLAW System (hooks and rods)

**Common or Usual Name**

1. Bone fixation cerclage
2. Pedicle screw system

**Classification Name**

1. 21 CFR § 888.3010, Bone fixation cerclage; Product Code: OWI
2. 21 CFR § 888.3070, Pedicle screw spinal system; Product Codes: NKB, OSH, MNI, MNH; 21 CFR § 888.3050, Spinal interlaminal fixation orthosis ; Product Code: KWP

**Predicate and Reference Devices**

1. Implanet S.A. JAZZ System (K151740) (primary predicate for JAZZ CLAW connector)

2. Implanet S.A. Spinal System (K143731) (primary predicate for JAZZ CLAW System (hooks and rods)); Synthes Cervifix System (K030377) (reference for JAZZ CLAW System (hooks and rods))

**Intended Use / Indications for Use**

1. The JAZZ CLAW connector consists of temporary implants to be used in orthopedic surgery. The JAZZ CLAW connector 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 spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ CLAW connector 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.

2. The Jazz Claw System (hooks and rods) 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 Jazz Claw System (hooks and rods) is intended for posterior 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 (fracture or dislocation);
- spinal stenosis;
- spinal deformities (scoliosis, kyphosis and/or lordlosis)
- tumor;
- pseudarthrosis; and
- revision of a failed fusion attempt.

The Jazz Claw System (hooks and rods) is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft.

**Device Description / Technological Characteristics**

The JAZZ CLAW System consists of the JAZZ CLAW hook and JAZZ CLAW rod.

The JAZZ CLAW connector and the cleared JAZZ braid are also separate components, as well as manual surgical instruments.

**Technological Comparison**

The technological differences with the JAZZ CLAW connector and the JAZZ CLAW System (hooks and rods) in comparison to the predicates for each device are minor. Both the JAZZ CLAW connector and the JAZZ System consist of a connector that attaches to the rods of a pedicle screw system (i.e., the JAZZ CLAW System (hooks and rods) and contains a braid to “wire” the surrounding bony structure.

The JAZZ CLAW System (hooks and rods) also contains an additional component, a laminar hook. This hook is similar to other hooks cleared in pedicle screw systems, such as the Implanet Spine System (K143731), and provides an additional attachment point to the spine. The addition of the hook does not raise different safety or effectiveness questions as it is a component typically included in pedicle screw systems to which the JAZZ CLAW connector

attaches. Thus, the modification to include a hook simply supplies the surgeon with an alternate method to add a laminar hook to the previously cleared Implanet Spine System.

Both the JAZZ CLAW connector and the cleared JAZZ System use established connection mechanisms. Specifically, both the JAZZ System and the JAZZ CLAW connector contain an internal screw used to tighten the device onto a rod. For the cleared JAZZ system, the rod is part of a separately cleared pedicle screw system while the JAZZ CLAW is connected to the JAZZ CLAW System (hooks and rods) via a rod dedicated for the hook. The JAZZ CLAW System also contains a set screw locking mechanism, identical to the locking mechanism cleared with the ISS pedicle screw system (K143731). The hook also attaches to its dedicated rod via the same set screw mechanism.

**Performance Data**

The strength of the overall construct (JAZZ CLAW connector used with hooks and rods) was assessed per ASTM F1717 dynamic axial compression testing and found to be equivalent to the predicate JAZZ system (K151740) and Implanet Spinal System (K143731). In addition, engineering rationales were performed to support device performance of the JAZZ CLAW connector and the JAZZ CLAW System (hooks and rods).

**Substantial Equivalence**

The JAZZ CLAW connector is substantially equivalent to the cleared JAZZ System. The JAZZ CLAW System (hooks and rods) are substantially equivalent to the cleared Implanet Spinal System and Synthes Cervifix System. The subject devices have the same intended uses and indications, and similar technological characteristics, and principles of operation as their associated predicate devices. The minor technological differences between the subject devices and the predicate devices raise no new issues of safety or effectiveness.