DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 31, 2016

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

Re: K153348
Trade/Device Name: JAZZ LOCK
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: February 25, 2016
Received: February 25, 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" (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 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 below.

510(k) Number *(if known)*
K153348

Device Name
JAZZ LOCK

Indications for Use *(Describe)*
JAZZ LOCK is a temporary implant to be used in orthopedic surgery. JAZZ LOCK is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. JAZZ LOCK is designed for a posterior approach. The indications for use include the following applications:

- Spinal trauma surgery: Jazz Lock implants can be used in sublaminar wiring technique
- Spinal degenerative surgery: Jazz Lock implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

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)

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510(k) SUMMARY

Implanet, S.A.'s JAZZ LOCK

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: November 18, 2015

Name of Device

JAZZ LOCK

Common or Usual Name

Bone fixation cerclage

Classification Name

21 CFR § 888.3010, Bone fixation cerclage; Product Code: OWI- bone fixation cerclage, sublaminar, Class II

Predicate and Reference Devices

Pioneer Surgical (now RTI Surgical)'s Songer Spinal Cable (K922952, K941213) (primary)
Implanet S.A.'s JAZZ System (K151740) (additional)

Intended Use / Indications for Use

The JAZZ LOCK is a temporary implant to be used in orthopedic surgery. JAZZ LOCK is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. JAZZ LOCK is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: Jazz Lock implants can be used in sublaminar wiring technique;

2. Spinal degenerative surgery: Jazz Lock implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

Device Description

The JAZZ LOCK consists of the following components and accessories: Titanium alloy Ti6Al4V locking base; PEEK Optima LT1 locking insert; polyester (polyethylene-terephthalate) braid; and stainless steel malleable strip and buckle. The braid is passed through the locking insert and around the pertinent spinal anatomy. The locking insert is compressed as it snaps into the locking base, locking the braid in place. The system also contains device-specific instrumentation used to position and tension the braid and lock the insert to the base.

Performance Data

In support of this 510(k) Premarket Notification, Implanet, S.A. has conducted bench testing to demonstrate that the JAZZ LOCK provides adequate mechanical strength for its intended use. The testing included static and dynamic testing of the construct strength of the JAZZ LOCK and static testing to determine propensity of the device to cut into bone. All bench testing confirmed that the product met the necessary specifications and is equivalent to the predicate. Creep testing of the braid showed adequate resistance to plastic deformation. In addition, the biocompatibility of the device has been confirmed in accordance with ISO 10993. The Company has conducted sterilization and shelf life validation in accordance with recognized industry standards.

Substantial Equivalence

The technological differences between the JAZZ LOCK and its primary predicate, the Pioneer Songer Spinal Cable System, are minor. Both the JAZZ LOCK and the Songer Spinal Cable System use cables to secure spinal anatomy. Both systems can be used on their own or in conjunction with other spinal hardware. Although the predicate's "wire" components are made from metal rather than polymer, bench testing shows the Jazz braid used with JAZZ LOCK has at least equivalent mechanical properties and performance compared to metallic braids or wires. Bench testing also demonstrates that the wider contact area and softer nature of the polyester braid offers at least equivalent performance in regards to the risk of wire damaging the bone.

Additionally, the Songer Spinal Cable System is meant to be used with flat or round bars and eyelets and then crimped to secure its position. In contrast, the JAZZ LOCK braid is combined with a locking connector to prevent its unwrapping and maintain tension. This is similar to the method employed by the JAZZ system (K151740), which connects to rods. With the cleared JAZZ system, an internal screw is used to tighten the connector around the rod, while the force in the JAZZ LOCK is applied by elastic deformation of the PEEK insert in its metallic housing.

The JAZZ LOCK contains an insert made from PEEK Optima LT1, which conforms to ASTM F2026. The use of this material in spinal applications is well established and poses no additional biocompatibility risks. Therefore, although technological differences exist between the systems, the differences do not raise different types of safety or efficacy questions and bench testing has demonstrated equivalent performance.

The JAZZ LOCK is substantially equivalent to the Songer Spinal Cable System.

Conclusion

The JAZZ LOCK has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the JAZZ LOCK and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the JAZZ LOCK is substantially equivalent to the Songer Spinal Cable System.