DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Implanet S.A.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street
29th Floor
Philadelphia, Pennsylvania 19103

January 19, 2017

Re: K162764
Trade/Device Name: Jazz Frame System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 23, 2016
Received: December 23, 2016

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 below

510(k) Number *(if known)*

K162764

Device Name

JAZZ Frame System

Indications for Use *(Describe)*

The Jazz Claw System (hooks and rods) and the Jazz Frame System are 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) and the Jazz Frame System are 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 (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis or revision of a failed fusion attempt.

The Jazz Claw System (hooks and rods) and the Jazz Frame System 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.

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 Frame System

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

Implanet S.A.
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Contact Person: Janice M. Hogan, Regulatory Counsel, Hogan Lovells US LLP

Date Prepared: January 18, 2016

Name of Device

JAZZ Frame System

Common or Usual Name

Thoracolumbosacral Pedicle Screw System

Classification Name

Thoracolumbosacral Pedicle Screw System

Primary Product Code

NKB

Regulation Number

21 CFR § 888.3070

Device Class

Class II

Predicate Devices

Implanet S.A.'s Implanet Spine System (ISS) (K132303) (primary)
Implanet S.A.'s JAZZ System (K151740) (additional)
Renovis S100 Pedicle Screw System (K101682, K111940) (additional)

Intended Use / Indications for Use

The Jazz Claw System (hooks and rods) and the Jazz Frame System are 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) and the Jazz Frame System are 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 (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis or revision of a failed fusion attempt.

The Jazz Claw System (hooks and rods) and the Jazz Frame System 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.

Device Description

The JAZZ Frame spinal implants are spinal fixation devices consisting of the following components: T-bars, straight rods, connectors, and surgical instruments. The T-bars are fixed closed transverse connectors. The rods have been previously cleared as part of the ISS system and are used with the JAZZ Frame. The JAZZ Connector and JAZZ Braid have been previously cleared and are also used with the JAZZ Frame. There is no change to the previously cleared JAZZ instruments.

Once the fusion rods have been bent to the desired shape, a T-bar is positioned at the top and middle of the two bars, and then tightened in place using the screwdriver. The caudal parts of the rods are inserted into heads of pedicle screws that have been previously implanted. The cranial end of the construct is then secured with JAZZ Connectors, and the screws of the T-bars undergo final tightening.

Technological Characteristics

The purpose of this 510(k) is to add the JAZZ Frame System to the JAZZ Systems. The JAZZ Frame consists of T-bars and 500 or 600 mm straight rods of various diameters. The construct is anchored to the spine using the previously cleared JAZZ Connectors. The only components not previously cleared are the T-bar connectors.

Performance Data

Static axial, rotational, and bending testing per ASTM F1798. Bacterial endotoxin testing (BET) as specified in ANSI/AAMI:ST72:2011 is used for pyrogenicity testing to achieve the Endotoxin limit of <20EU/Device.

Substantial Equivalence

The JAZZ Frame is substantially equivalent to existing ISS and JAZZ Systems. Interconnection strength testing has shown the T-bars to possess at least equivalent gripping strength to the crosslink components of the ISS. The JAZZ Frame has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the JAZZ Frame and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the JAZZ Frame is substantially equivalent to its predicates.