510(k) SUMMARY

Implanet S.A.'s IMPLANET Spine System

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

Implanet S.A.
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Contact Person: Franck Rigal, Director of Quality and Regulatory Affairs

Date Prepared: September 15, 2013

Name of Device

IMPLANET Spine System

OCT 10 2013

Common or Usual Name

Spinal fixation device

Classification Name

888.3070 – Spinal Pedicle Fixation Orthosis - NKB, OSH, MNI, MNH

888.3050 – Spinal Interlaminal Fixation Orthosis - KWP

Predicate Devices

Implanet S.A.'s Calypso System (K120564)

Medtronic Sofamor Danek's CD HORIZON® Spinal System (K091445)

Intended Use / Indications for Use

The IMPLANET Spine System 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 IMPLANET Spine System is intended for posterior, non-cervical pedicle and non-pedicle 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.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the IMPLANET Spine System implants 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 IMPLANET Spine System is a posterior instrumentation system. The polyaxial screws are made of Ti6Al4V titanium alloy compliant with ISO 5832-3. The polyaxial screw is comprised of three sections: the pedicle screw; the head; and a ring that connects the screw to the head. The polyaxial screws are offered in diameters ranging from 5.0 to 7.5 mm and in lengths ranging from 35 to 60 mm.

The monoaxial pedicle screws are made of Ti6Al4V titanium alloy compliant with ISO 583203 and are available in 5.0 mm, 6.0 mm, 7.0 mm, and 8.0 mm diameters. The screws range in length from 35 to 60 mm.

The system includes both straight and pre-bent rods made of Ti6Al4V titanium alloy.

The transverse connectors are composed of Ti6Al4V titanium alloy compliant with ISO 5832-3. These connectors are used to build a transverse connection between two union rods.

The hooks are made of Ti6Al4V titanium alloy and are provided in multiple configurations.

The IMPLANET Spine System has principles of operation substantially similar to other pedicle screw-based systems for the indications listed.

The IMPLANET Spine System components may be used for posterior pedicle screw fixation in pediatric cases: polyaxial and monoaxial screws, rods, transverse connectors and rods.

The purpose of the subject 510(k) notice is the addition of new indications and the inclusion of intermediate screw sizes to the company's cleared system.

Technological Characteristics

The IMPLANET Spine System consists of: monoaxial and polyaxial pedicle screws, union rods, transverse connectors, and hooks.

Performance Data

This 510(k) premarket notification incorporates by reference the bench testing performed in support of Implanet S.A.'s Calypso System (K120564), which is listed below. All bench testing confirmed that the product met the necessary specifications. Sterilization and shelf life validation testing conducted for the Calypso System in accordance with recognized industry standards are also incorporated by reference. In addition, the biocompatibility of the device was confirmed in accordance with ISO 10993. A list of the tests performed on the previous version of the device to support substantial equivalence is provided below:

- Static axial gripping capacity, static flexion/extension bending, static axial torque gripping capacity – ASTM F1798;
- Static compression bending – ASTM F1717;
- Static torsion – ASTM F1717;
- Dynamic compression bending – ASTM F1717;
- Shelf life – ASTM F 1980;
- Implant sterilization validation – ISO 11137;
- Instrument cleaning and sterilization validation – ISO 17665;
- Cytotoxicity – ISO 10993;
- Acute systemic toxicity – ISO 10993.

In addition, a list of the tests performed again on the current version of the device to support substantial equivalence is provided below:

- Cytotoxicity – ISO 10993;
- Chemical characterization – ISO 10993.

Substantial Equivalence

When used for pediatric use, the IMPLANET Spine System is substantially similar to Implanet S.A.'s Calypso System and Medtronic Sofamor Danek's CD HORIZON® Spinal System. The IMPLANET Spine System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the IMPLANET Spine System and its predicate devices raise no new issues of safety or effectiveness. Thus, the IMPLANET Spine System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

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

Re: K132303
Trade/Device Name: IMPLANET Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, MNI, MNH
Dated: July 24, 2013
Received: July 24, 2013

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 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

for Erin F. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132303

Device Name: IMPLANET Spine System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy S. Graf -S (for RPJ)

(Division Sign-off)
Division of Orthopedic Devices
510(k) Number: K132303