510(k) SUMMARY
K133152

JAN 2 2 2014

Stanmore Implants Worldwide Ltd.'s JTS® Extendible Distal Femoral Implant

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

Stanmore Implants Worldwide Ltd

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Facsimile:

Contact Person: Jon Charters

Date Prepared: September 30, 2013

Name of Device and Name/Address of Sponsor

JTS® Extendible Distal Femoral Implant

Stanmore Implants,
210 Centennial Avenue,
Centennial Park,
Elstree,
WD6 3SJ,
United Kingdom

Common or Usual Name

Limb salvage system

Classification Name

Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR 888.3510) - KRO

Predicate Devices

- JTS® Extendible Implant, Stanmore Implants Worldwide Ltd (K092138)
- METS® SMILES Total Knee Replacement, Stanmore Implants Worldwide Ltd (K120992)

- METS Modular Total Femoral Replacement, Stanmore Implants Worldwide Ltd (K121055)
- METS® Modular Distal Femur, Stanmore Implants Worldwide Ltd (K121029)

Purpose of the Special 510(k) notice.

The JTS® Extendible Distal Femoral Implant is a modification to the JTS® Extendible Implant.

Intended Use

The JTS® Extendible Distal Femoral Implant is intended to be used for cemented limb salvage procedures in paediatric (between the ages of 2 and 21) cases where radical resection and replacement of the distal femur is required with the following conditions:

- patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
- surgical intervention for severe trauma, revision knee arthroplasties, failed previous prosthesis and/or oncology indications; and
- malignant diseases (e.g., osteogenic sarcoma).

The JTS® Extendible Distal Femoral Implant and its components are for single use only.

Technological Characteristics

The JTS® Extendible Distal Femoral Implant is a patient specific system that is used to replace bone which is lacking or damaged or must be removed (e g., due to tumor). The device consists of components (defined below) which are available in a range of sizes depending on the size and needs of the patient. Every configuration includes a telescoping shaft with a gearbox, magnet, and extension screw assembly for extending the implant when required by the patient.

Components available in patient specific sizes:

- Femoral Telescoping Shaft
- Femoral Block
- Extension Screw
- Femoral Shaft
- Tibial configurations for knee joint including passive rotating hinge, fixed hinge, rotating hinge (polyethylene), and metal cased tibia components
- Passive Bearing
- Tibial Passive Stem
- HA Coated Extra-cortical Plate that is integral to the Femoral Shaft
- Hydroxyapatite Collar that is integral to the Femoral Shaft
- Bumper Pad
- Bushes
- Axles

The specific design of the implant is based on the surgeon's description of the case and patient radiological information. The key dimensions for each JTS® Extendible Distal femoral Implant are derived from the generic device specifications and by taking measurements from the patient's X-rays and/or CT scans. The implant is designed and manufactured for each patient.

The JTS® External Drive Unit is used periodically to lengthen the prosthesis when the patient's limb length discrepancy needs to be addressed. The JTS® External Drive Unit creates a magnetic field which interacts with the magnet in the telescoping shaft to lengthen the implant.

Substantial Equivalence

JTS® Extendible Distal Femoral Implant has the same intended use and similar principles of operation, and technological characteristics as the cleared JTS® Extendible Implant (K092138). The minor difference between the devices is that the current version of the device includes additional optional knee configurations, including fixed and rotating hinge tibial designs. These new knee components have already been cleared by FDA as part of the METS Smiles Total Knee Replacement (K120992), METS Total Femur (K121055) and the METS Distal Femur (K121029). In addition, extra small tibial components have been added to the system.

These additional knee configurations do not alter the fundamental scientific technology of the JTS® device or raise any new questions of safety or effectiveness. Thus, the JTS® Extendible Distal Femoral Implant is substantially equivalent to its predicate devices.

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

January 22, 2014

Stanmore Implants Worldwide, Limited
% Mr. Gerard J. Prud'homme
Partner
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K133152
Trade/Device Name: JTS® Extendible Distal Femoral Implant
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: December 23, 2013
Received: December 23, 2013

Dear Mr. Prud'homme:

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,

Ronald P. Jean -S for

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): K133152

Device Name: JTS® Extendible Distal Femoral Implant

Indications for Use:

The JTS® Extendible Distal Femoral Implant is indicated for cemented limb salvage procedures in paediatric (between the ages of 2 and 21) cases where radical resection and replacement of the distal femur is required with the following conditions:

- patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
- surgical intervention for severe trauma, revision knee arthroplasties, failed previous prosthesis and/or oncology indications; and
- malignant diseases (e.g., osteogenic sarcoma).

The JTS® Extendible Distal Femoral Implant and its components are for single use only

Prescription Use __X___ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices