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510(k) SUMMARY

Stanmore Implants Worldwide Ltd
JTS® Extendible Implant

Preparation Date:	March 17, 2011
Applicant/Sponsor:	Stanmore Implants Worldwide Ltd 210 Centennial Avenue Centennial Park Elstree WD6 3SJ Phone: + 44 (0) 20 8238 6500 Facsimile: + 44 (0) 20 8953 7443
Contact Person:	Jon Charters QA/RA Manager
Proprietary name:	JTS® Extendible Implant
Common or Usual Name:	Limb sparing system
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 C.F.R. § 888.3510)

Predicate Devices

- Wright Medical Technology Inc., Repiphysis Limb Salvage System (K021489)
- Howmedica (Stryker) Global Modular Replacement System (K023087)

Intended Use / Indications for Use

The JTS® Extendible Implant is intended to be used for cemented limb sparing 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 prostheses and/or oncology indications; and malignant diseases (e.g., osteogenic sarcoma).

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

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Implant Description

The JTS® Extendible 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 JTS® Extendible Implant is a distal femoral (passive hinge tibia) implant. 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
- Passive Hinge
- 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 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.

Performance Testing

The following testing was provided to support a claim of substantial equivalence to the predicate devices:

- Gearbox output shaft seal testing
- MRI Environment Testing
- Computer Topography (CT) Testing
- Axle shear stress
- Fatigue testing of the knee joint
- Axle shear stress evaluation

- Rotational laxity of tibial component
- Range of motion of JTS® Extendible Implant rotating hinge knee
- Wear test JTS® Extendible Implant
- Contact Stress
- Fatigue testing for JTS® Extendible Implant
- EMC test for JTS® Extendible Implant Drive Unit
- Electrical safety test for JTS® Extendible Implant External Drive Unit
- Torsional resistance testing of the femoral shaft-knee interface
- Contact stress evaluation of femoral component with the polymeric bumper pad
- FEA analysis of the contact stresses in the bushes of the JTS® Extendible Implant knee
- Summary of clinical data of compassionate use patients and foreign patients implanted with the JTS® Extendible Implant

Substantial Equivalence

The JTS® Extendible Implant is substantially equivalent to the Repiphysis Limb Salvage System and the Global Modular Replacement System. The JTS® Extendible Implant has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the JTS® Extendible Implant and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the JTS® Extendible Implant is as safe and effective as Repiphysis Limb Salvage System and the Global Modular Replacement System. Thus, the JTS® Extendible Implant is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Stanmore Implants Worldwide, Ltd.
% Mr. Gerard J. Prud'homme, Esq.
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004

MAR 2 2 2011

Re: K092138
Trade/Device Name: JTS® Extendible Implant
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: July 30, 2010
Received: July 30, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K092138

Device Name: JTS® Extendible Implant

Indications for Use:

The JTS® Extendible Implant is indicated for cemented limb sparing 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 prostheses and/or oncology indications; and malignant diseases (e.g osteogenic sarcoma).

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

Prescription Use Yes
(Part 21 C.F.R. 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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