K120992 (1/2)

SEP 5 2012

SECTION 5:
510(k) SUMMARY

Preparation Date	**5th September 2012**
Trade Name	**METS® SMILES TOTAL KNEE REPLACEMENT.**
Classification Name	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
Applicant/Sponsor	Stanmore Implants Worldwide Ltd 210 Centennial Avenue Centennial Park Elstree WD6 3SJ United Kingdom Phone: + 44 (0) 20 8238 6503 Facsimile: +44 (0) 20 8954 0351
Contact Person:	Nancy MacDonald Manager of Regulatory Affairs Health Policy Associates Inc. Email: nmacdonald@healthpolicyassociates.com Tel: (781) 329-2993 Fax: (781) 329-2958
Equivalent to	JTS Extendible Implant, Stanmore Implants (K092138), AVL Hinge Knee Biomet (K051570) and the Repiphysis Limb Salvage System Wright Medical (K021489)
Device Description	The single use METS® Smiles Total Knee Replacement is intended for the replacement of diseased or deficient bone in the proximal tibia. The femoral component and tibial stems of the system are intended for cemented use only. The system comprises of the following components: • Small and standard anatomical femoral knee components with single sized stem for each femoral component; • A range of tibial options in both small and standard sizes – plastic cased rotating hinge, metal cased rotating hinge or fixed hinge; • A series of tibial and femoral plateau plates in both knee sizes; • Hyper-extension bumper pad for soft hyper-extension stop for both knee sizes; • A pair of bushes, axle and a circlip for both knee sizes.

	The materials used in the manufacture of the systems include: titanium (Ti), cobalt-chromium-molybdenum (CoCrMo) and ultra high molecular weight polyethylene (UHMWPE).
Intended Use	The METS® Smiles Total Knee Replacement is intended for the replacement of diseased or deficient bone around the knee joint.
Indications for Use	1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis 2. Correction of varus, valgus or post traumatic deformity 3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement 4. Ligament deficiencies 5. Tumor resections 6. Revision of previously failed total joint arthroplasty 7. Trauma The METS® Smiles Total Knee Replacement is for cemented use only. The METS® Smiles Total Knee Replacement and its components are for single use only.
Performance Data (non-clinical and clinical)	Non Clinical Testing The results of the non-clinical performance testing demonstrate that the device is safe and effective and substantially equivalent to the predicate devices. The Performance testing included : knee fatigue and wear test, disassembly force testing for the taper connections, ASTM F1800-07 testing. Clinical Performance Conclusions Clinical evaluation was carried out based upon published papers and post market surveillance.
Substantial Equivalence	The METS® Smiles Total Knee Replacement is equivalent to the JTS Extendible Implant, (K092138), AVL Hinge Knee (K051570) and the Repiphysis limb salvage system (K021489) predicate devices. The determination of substantial equivalence is based on the similarity of the intended use, indications for use, design / technological characteristics, materials of composition, method of sterilization, performance data and clinical evaluation.

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, Limited
% Health Policy Associates, Incorporated
Ms. Nancy MacDonald
Manager of Regulatory Affairs
690 Canton Street, Suite 302
Westwood, Massachusetts 02090

SEP 5 2012

Re: K120992
Trade/Device Name: METS® SMILES TOTAL KNEE REPLACEMENT
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: August 2, 2012
Received: August 3, 2012

Dear Ms. MacDonald:

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,

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

Enclosure

K120992

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: **METS® SMILES TOTAL KNEE REPLACEMENT.**

Intended Use:

The METS® Smiles Total Knee Replacement is intended for the replacement of diseased or deficient bone around the knee joint.

Indications for Use:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor resections
6. Revision of previously failed total joint arthroplasty
7. Trauma
8. The fixed hinge tibial component is intended for limb salvage procedures requiring radical resection of bone and soft tissue

The METS® Smiles Total Knee Replacement is for cemented use only.

The METS® Smiles Total Knee Replacement and its components are for single use only

Prescription Use__X__ AND/ OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (Per 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)

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

510(k) Number K120992