August 12, 2021

Stanmore Worldwide Implants Ltd.
Dan Clarke
Regulatory and Compliance Officer
210 Centennial Avenue
Centennial Park
Elstree, WD6 3SJ
United Kingdom

Re: K140900
Trade/Device Name: Patient Specific 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

Dear Dan Clarke:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 12, 2015. Specifically, FDA is updating this SE Letter to correct a typo in the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ting Song, Ph.D., OHT6: Office of Orthopedic Devices, 301-796-7677, Ting.Song@fda.hhs.gov.

Sincerely,

Ting Song -S

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

February 12, 2015

Stanmore, Incorporated
Mr. Dan Clarke
Director of Regulatory Affairs
210 Centennial Avenue, Centennial Park
Elstree WD6 3SJ
United Kingdom

Re: K140900
Trade/Device Name: Patient Specific 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: January 14, 2015
Received: January 16, 2015

Dear Mr. Clarke:

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" (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 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 yours,

Lori A. Wiggins -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: To be assigned K140900

Device Name: Patient Specific SMILES Total Knee Replacement

Indications for Use: The Patient Specific SMILES Total Knee Replacement is intended for the replacement of diseased or deficient bone around the knee joint. It is indicated for:

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

The Patient Specific SMILES Total Knee Replacement and its components are for cemented use only.

The Patient Specific Patient Specific SMILES Total Knee Replacement and its components are for single use only.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Proprietary Name: Patient Specific SMILES Total Knee Replacement

Common Name: Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer

Classification Regulation: 21 CFR 888.3510

Submitter's Name: Stanmore Worldwide Implants Ltd.
Address: 210 Centennial Avenue
Centennial Park
Elstree
WD6 3SJ UNITED KINGDOM

Contact Person: Jon Charters
Telephone Number: +44-20-8238-6500
Fax Number: +44-20-8953-7443

Date Summary Prepared: March 31, 2014

Device Description

The Patient Specific SMILES Total Knee Replacement is a patient-specific system that is intended for the replacement of diseased or deficient bone around the knee joint. The system includes three tibial options: 1) metal cased rotating hinge, 2) fixed hinge, and 3) rotating hinge polyethylene tibia. The Patient Specific SMILES Total Knee Replacement and its components are intended for cemented use only.

The materials used in the manufacture of the Patient Specific SMILES Total Knee Replacement include titanium (Ti), cobalt-chromium-molybdenum (Co-Cr-Mo) and ultra-high molecular weight polyethylene (UHMWPE).

The device is for single use only.

Purpose of Submission

This Premarket Notification is being submitted as a modification to the METS® SMILES Total Knee Replacement to add patient-specific components and an extra-small option for the knee.

Intended Use

The Patient Specific SMILES Total Knee Replacement is intended for the replacement of diseased or deficient bone around the knee joint. It is indicated for:

- Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis

- Correction of varus, valgus or post traumatic deformity
- Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
- Ligament deficiencies
- Tumor resection
- Revision of previously failed total joint arthroplasty
- Trauma
- The fixed hinge tibial component is intended for limb salvage procedures requiring radical resection of bone and soft tissue

The Patient Specific SMILES Total Knee Replacement and its components are for single use only.

The Patient Specific SMILES Total Knee Replacement and its components are for cemented use only.

Predicate Device(s)
The predicate devices are the METS® SMILES Total Knee Replacement cleared on September 5, 2012 (K120992), the JTS® Extendible Distal Femoral Implant cleared on March 22, 2011(K092138) and the JTS® Extendible Distal Femoral Implant cleared on January 22, 2014 (K133152).

Technological Characteristics
The Patient Specific SMILES Total Knee Replacement is a patient-specific implant system that is used to replace diseased or deficient bone around the knee joint.

The Patient Specific SMILES Total Knee Replacement is based on the surgeon's prescription and the patient radiological information. The implant is designed and manufactured for each patient.

The Patient Specific SMILES Total Knee Replacement is provided sterile by gamma irradiation.

Substantial Equivalence
The Patient Specific SMILES Total Knee Replacement has the same intended use and technological characteristics as the METS® SMILE Total Knee Replacement (K120992). The difference between the two implant systems is that the current version includes patient-specific components and an extra-small option for the knee. These new components have been cleared previously by FDA as part of the JTS® Extendible Distal Femoral Implant (K092138 and K133152).

Performance Data
The Patient Specific SMILES Total Knee Replacement has been evaluated through non-clinical performance testing for fatigue and wearing testing of the knee and ASTM F1800-07 testing. The Patient Specific SMILES Total Knee Replacement met all of the acceptance criteria.

The Patient Specific SMILES Total Knee Replacement does not alter the fundamental scientific technology of the METS® SMILES Total Knee Replacement, alter the indication for use or raise

any new questions of safety or effectiveness. Therefore, the Patient Specific SMILES Total Knee Replacement is substantially equivalent to its predicate device.