K122277

OCT 2 2 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 372-1718
Establishment Registration Number	1825034
Name of contact person	Elizabeth Wray
Date prepared	July 25, 2012
Name of device	
Trade or proprietary name	Oxford Fixed Lateral Bearing Partial Knee Replacement
Common or usual name	Unicondylar Knee Prosthesis
Classification name	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis (21CFR §888.3530)
Classification panel	Orthopedic
Regulation	21CFR §888.3530
Product Code(s)	HRY
Legally marketed device(s) to which equivalence is claimed	K042093 Vanguard M Series Unicondylar Tibial Bearings K011138 Oxford Unicompartmental Knee Femoral Component
Reason for 510(k) submission	New Device Construct
Device description	The Oxford Fixed Lateral Bearing Partial Knee Replacement is a partial knee replacement option that consists of a legally marketed femoral component (single and twin peg versions) manufactured from CoCrMo (ASTM F-75), a tibial tray/plate manufactured from CoCrMo (ASTM F-75), and a fixed tibial bearing of direct compression molded (DCM) polyethylene (UHMWPE) conforming to ASTM F-648 which is molded onto the tibial tray. The femoral and tibial tray

	components have a coarse grit blast surface finish the same as that of the predicates. The tibial component (metal tray plus polyethylene) will be available in 6 sizes (A, B, C, D, E and F) and 5 overall thicknesses (8.0, 9.0, 10.0, 11.0, 12.0mm). The subject tibial component is D-shaped. The subject device is indicated for lateral use only for cemented use fixation.
Intended use of the device	Unicondylar Knee implant intended to replace part of a knee joint when used in conjunction with a femoral and tibial component.
Indications for use	Partial replacement of the articulating surfaces of the knee when only one side of the knee joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous partial arthroplasty in the affected compartment. The Oxford Fixed Lateral bearings are indicated for use in the lateral compartment and intended to be implanted with bone cement. The Oxford Femoral components are indicated for use in the lateral compartment for a fixed bearing application. They are intended to be implanted with bone cement.

Summary of the technological characteristics of the device compared to the predicate

The Oxford Fixed Lateral Bearing Partial Knee Replacement is a partial knee replacement option that consists of a legally marketed femoral component (single and twin peg versions) manufactured from CoCrMo (ASTM F-75), a tibial tray/plate manufactured from CoCrMo (ASTM F-75), and a fixed tibial bearing of direct compression molded (DCM) polyethylene (UHMWPE) conforming to ASTM F-648 which is molded onto the tibial tray. The biocompatible materials of the components are identical to the predicates and have a long history of orthopedic use. The tibial component is D-shaped for lateral use while the K042093 tibial component is tear shaped for lateral and medial use. Both the subject tibial component and the K042093 predicate incorporate a keel. The subject device is indicated only for cemented use fixation as in predicates. A tabular summary of the

technological characteristics is provided below.

Characteristic	Subject Device	Predicate
Design – Femoral	Single and Twin Pegged Femorals	K011138
Design – Tibial	D-Shaped	K042093
Material	Co-Cr-Mo UHMWPE	K042093 K011138
Principal of operation	Replace articulating surfaces of knee	K042093 K011138
Dimensions - Femoral	X-small, Small, Med, Large, X-Large	K011138
Dimensions – Tibial Component	A, B, C, D, E, F	K042093

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

The Oxford Fixed Lateral Partial Knee Replacement components have the same basic technological characteristics as the predicate devices except for slight modifications to the general design as described in this 510(k) notification. Preclinical performance tests/rationales were provided to address the subject construct's Contact Area, Range of Motion, and Tibial Strength. A Magnetic Resonance rationale was also provided. Results indicate that the subject construct is substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: None provided as a basis for substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of preclinical tests/engineering rationales and the similarities with legally marketed devices indicate the devices will perform within the intended use, and do not raise any new safety and efficacy issues.

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

Biomet Manufacturing Corp.
% Ms. Elizabeth Wray
Senior Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

OCT 2 2 2012

Re: K122277
Trade/Device Name: Oxford Fixed Lateral Bearing Partial Knee Replacement
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: July 26, 2012
Received: July 30, 2012

Dear Ms. Wray:

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

510(k) Number (if known): K122277

Device Name: Oxford Fixed Lateral Bearing Partial Knee Replacement

Indications For Use:

Partial replacement of the articulating surfaces of the knee when only one side of the knee joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous partial arthroplasty in the affected compartment.

The Oxford Fixed Lateral bearings are indicated for use in the lateral compartment and intended to be implanted with bone cement.

The Oxford Femoral components are indicated for use in the lateral compartment for a fixed bearing application. They are intended to be implanted with bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(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)

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

510(k) Number K122277