BIOMET
MANUFACTURING CORP.

SEP 0 3 2013

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) 371-1027
Establishment Registration Number	1825034
Name of contact person	Elizabeth Wray
Date prepared	December 14, 2012
Name of device	
Trade or proprietary name	Prelude™ PF Resurfacing Knee System
Common or usual name	Unicondylar Knee Prosthesis
Classification name	Knee joint patello-femoral resurfacing prosthesis
Classification panel	Orthopedic
Regulation	21CFR §888.3540
Product Code(s)	KRR
Legally marketed device(s) to which equivalence is claimed	Arthrosurface Hemicap Patello-femoral Resurfacing System (K060127/K071413) Mako Patellofemoral Knee Implant System (K080029/K082088) Vanguard Patella Components (K040770) Vanguard CR Femoral Component (K023546)
Reason for 510(k) submission	New Device
Device description	The Prelude™ Patellofemoral (PF) Resurfacing Knee System is a patellofemoral resurfacing prosthesis incorporating a distal femoral trochlear surface articular component and a patella component. The cast femoral component is manufactured from CoCrMo (ASTM F-75) and the MIM femoral component is manufactured from CoCrMo (ASTM F-2886) both with a porous undersurface coating of titanium alloy (ASTM F-1580) the patella component is manufactured

P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: (800) 348-9500
Office: 574 267 6639
Main Fax: 574 267 8137
www.biomet.com

	from polyethylene (UHMWPE) conforming to ASTM F-648 with a stainless steel x-ray wire. The implant system is intended to be implanted with bone cement.
Intended use of the device	Resurfacing of the patella-femoral joint; cemented use.
Indications for use	The Prelude™ PF Resurfacing Knee System is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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

The Prelude PF Resurfacing Knee System femoral components are comprised of CoCrMo and will be available for cemented application for fixation to the prepared femoral. The femoral component is to replace the damaged portion of the focal defect in the trochlear groove of the femur in the patient and restore normal knee function similar to the movement of a natural knee. The predicate device femoral components are also comprised of CoCrMo for cemented application and are similar to the Prelude PF femoral components in design and dimension.

The Prelude PF Resurfacing Knee System patella components are comprised of polyethylene (UHMWPE) and intended for cemented application available in either single or three-peg options for fixation. These patella components are identical to the Vanguard Series A patella components (K040770) and similar to the patellofemoral predicate patella component designs.

A tabular summary of the technological characteristics is provided below.

Characteristic	Subject Device	Predicate
Design – Femoral	Variation in curvature of articulating surface, central keel	K060127 / K071413
Design – Patella	Single-peg and Three-peg	K040770
Material	Co-Cr-Mo UHMWPE	K060127/K071413 K080029/K082088 K040770
Principal of operation	Replace articulating surfaces of knee	K060127/K071413

P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800 345 9500
Other: 574 267 6639
Main Fax: 574 267 8137
www.biomet.com

		K080029/K082088
Dimensions - Femoral	9 options: 1-6 and 6W, 7W, and 8W	K060127/K071413
Dimensions – Patella	25mm x 8mm, 28mm x 8mm, 31mm x 8mm, 25mm x 6.2mm, 28 x 6.2mm, and 31mm x 6.2mm	K040770

PERFORMANCE DATA

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

Performance Test Summary-New Device

The Prelude™ PF Resurfacing Knee System has 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, Fatigue Strength, and Surface Finish. A Magnetic Resonance rationale was also provided. Results indicate that the subject construct is substantially equivalent to legally marketed devices.

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.

P.O. Box 587
Warsaw, IN 46581-0587
Toll Free 800.348.9570
Office 574.267.6639
Main Fax 574.267.8137
www.biomet.com

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

Biomet Manufacturing Company
Ms. Elizabeth Wray
Regulatory Project Manager
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

September 3, 2013

Re: K123907
Trade/Device Name: Prelude PF Resurfacing Knee System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patella-femoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: July 30, 2013
Received: August 1, 3013

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 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" (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 -S

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

Enclosure

Indications for Use

510(k) Number (if known): K123907

Device Name: Prelude PF Resurfacing Knee System

Indications For Use:

The Prelude™ PF Resurfacing Knee System is intended to be used in cemented patella-femoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices