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AUG 30 2011

Summary of Safety and Effectiveness
Attune Total Knee System – PS Femoral Components and PS Fixed Bearing Inserts
DePuy Orthopaedics

Submitted by: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581
Phone: (574) 371-4923
Fax: (574) 371-4987

Contact Person: Nancy Friddle, Project Manager Regulatory Affairs

Date Prepared: May 16, 2011

Proprietary Name: DePuy Attune™ Knee System

Common Name: Total Knee Replacement Prosthesis

Classification Name: 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Class II

Product Code: JWH
OIY

Predicate Devices: The DePuy Attune PS Femoral Components and PS Fixed Bearing Inserts, which are part of the DePuy Attune Knee System, are substantially equivalent to currently marketed devices including:

- Attune Knee System, K101433
- Sigma Tibial Inserts, K033272
- Sigma XLK Tibial Inserts, K040166
- Sigma PS Femoral Components, K073529
- Zimmer NexGen LPS Femoral Components /Articular Surfaces, K960279

Device Description: The Attune™ posterior stabilized (PS) femoral components have an asymmetric trochlear groove and are available in sizes 1-10 in right and left options. Sizes 3-6 are available in standard and narrow options. The fixation surface is textured. It incorporates two lugs (pegs) to provide additional stability and recessed cement pockets for enhanced cement fixation. The Attune femoral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75.

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The Attune PS fixed bearing tibial insert is designed with a topography that, in the sagittal view, consists of multiple radii. The sagittal anterior radii are relatively conforming to the femoral component to aid in anterior constraint while the posterior radius is less conforming to allow rollback. The Attune PS fixed bearing tibial inserts are available in sizes 1-10 and in thicknesses of 5, 6, 7, 8, 10, 12, 14, 16, 18, 20, and 22mm. The inserts are manufactured from AOX ultra high molecular weight polyethylene conforming to ASTM F648.

The Attune PS femoral components and PS fixed bearing inserts are compatible with the Attune FB tibial bases (K101433) and patellae (K103756).

The Attune PS Total Knee is designed to accommodate knee flexion to 145 degrees in those patients able to attain a high degree of knee flexion.

Intended Use: Total knee replacement is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

The Attune PS Total Knee is intended to accommodate knee flexion to 145 degrees in those patients able to attain a high degree of knee flexion.

Indications for Use: As part of the DePuy Attune Knee System, the DePuy Attune PS femoral components and tibial inserts are intended for cemented use as a total knee replacement system.

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

Technological Characteristics: As shown in the following tables, the technological characteristics of the Attune PS femoral components and tibial inserts are similar to the predicate devices including design and material.

Characteristic	Attune PS Femoral Component	Attune CR Femoral Component (K101433)
Material	Cast Co-Cr-Mo alloy conforming to ASTM F75	Cast Co-Cr-Mo alloy conforming to ASTM F75

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Characteristic	Attune PS Femoral Component	Attune CR Femoral Component (K101433)
Sizes	Sizes 1 to 10 standard, Left and Right Sizes 3-6 narrow, Left and Right Proportional Sizing	Sizes 1 to 10 standard, Left and Right Sizes 3-6 narrow, Left and Right Proportional Sizing
Fixation Surface	Cemented	Cemented

Characteristic	Attune PS Fixed Bearing Tibial Inserts	Attune CR Fixed Bearing Tibial Inserts (K101433) and Sigma Tibial Inserts (K033272)
Material	AOX UHMWPE conforming to ASTM F648	Attune CR: AOX UHMWPE conforming to ASTM F648
Sizes	Proportional sizing PS inserts, sizes 1 to 10 Actual thicknesses 5, 6, 7, 8, 10, 12, 14, 16, 18, 20, and 22mm.	Attune CR: Proportional sizing CR inserts, sizes 1 to 10 Actual thicknesses 5, 6, 7, 8, 10, 12, 14, 16, and 18mm. Sigma Stabilized: Constant sizing Stabilized inserts, sizes 1.5 to 6 Composite thicknesses 8, 10, 12.5, 15, 17.5, 20, 22.5 and 25mm.

Summary of Substantial Equivalence:

The DePuy Attune Total Knee System is substantially equivalent to currently marketed devices as demonstrated with preclinical data.

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Non-Clinical Testing:

Functional testing was conducted in compliance with FDA guidance, Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA, to verify that the implant performance would be substantially equivalent to predicate devices for anticipated in vivo loading via various constraint, contact, wear, and fatigue tests.

Clinical Testing:

None provided as it was not necessary to determine substantial equivalence between the Attune Knee System's PS femoral and PS fixed bearing insert components and the predicate devices.

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

DePuy Orthopaedics, Inc.
% Ms. Nancy Friddle
700 Orthopaedic Drive
Warsaw, Indiana 46581

AUG 3 0 2011

Re: K111433
Trade/Device Name: DePuy Attune™ PS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH
Dated: August 10, 2011
Received: August 11, 2011

Dear Ms. Friddle:

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

2. INDICATIONS FOR USE

510(k) Number (if known): K111433

Device Name: DePuy Attune™ PS Knee System

Indications for Use:

The DePuy Attune™ Knee System is intended for cemented use as a total knee replacement system.

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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)

for M. Melkerson

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

510(k) Number K111433