

Summary of Safety and Effectiveness
Attune Total Knee
DePuy Orthopaedics

K101433 #1/6

Submitted by: DePuy Orthopaedics, Inc. DEC 10 2010
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Contact Person: Nancy Friddle, Project Manager Regulatory Affairs

Date Prepared: Aug 2, 2010

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 Knee System is substantially equivalent to currently marketed devices including:

- PFC Sigma® Knee System (cleared as the Darwin Knee System), K943462
- Sigma Patella (cleared as the Darwin Knee System), K950010
- PFC Cruciate Retaining Knee System, Size 1.5, K961685
- Sigma Co-Cr Tibial Trays, K032151
- Sigma XLK Tibial Inserts, K040166
- Sigma CR 150 Femoral Components, K082500
- Zimmer NexGen CR Knee System, K933785
- AMK® Fixed Stem Tibial Tray, K922620

Device Description: The Attune™ femoral components are available in a cruciate retaining (CR) version. The CR 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.

The Attune fixed bearing CR tibial insert is designed with a topography that, in the sagittal view, consists of multiple radii. The sagittal anterior radii are tight to aid in anterior constraint while the posterior radius is larger to allow rollback. The Attune design allows for the retained posterior cruciate ligament and/or

balanced posterior capsule to assist in appropriate rollback of the femur. The design offers minimal but appropriate constraint in the posterior direction for maximal rollback and full range of motion. The Attune fixed bearing CR tibial inserts are available in sizes 1-10 and in thicknesses of 5, 6, 7, 8, 10, 12, 14, 16, and 18mm. The inserts are manufactured from AOX ultra high molecular weight polyethylene conforming to ASTM F648.

The Attune tibial bases are available in sizes 1-10. The Attune tibial base fixation surface is textured. It incorporates a stem and keel to provide additional stability and recessed cement pockets for enhanced cement fixation. The Attune tibial base utilizes a central universal locking mechanism to capture the tibial insert. The Attune tibial bases are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75.

The Attune patellae are available in sizes 29, 32, 35, 38, and 41mm. The fixation surface incorporates 3 pegs to provide stability and recessed cement pockets for enhanced cement fixation. The patella components are manufactured from AOX ultra high molecular weight polyethylene conforming to ASTM F648.

The Attune Knee System is designed to accommodate knee flexion to 150 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 Knee System is intended to accommodate knee flexion to 150 degrees in those patients able to attain a high degree of knee flexion.

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.

Technological Characteristics:

As shown in the following tables, the technological characteristics of the Attune femoral components and tibial baseplates are similar to the predicate devices including design and CoCr material.

The technological characteristics of the Attune patellae and tibial inserts are similar to the predicate devices in terms of design. The AOX material has also been proven to be similar to that of predicate materials.

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Characteristic	Attune™ CR Femoral Component	PFC Sigma CR Femoral Component (K943462, K961685), PFC Sigma CR150 Femoral Component (K082500), and NexGen (K933785)
Material	Cast Co-Cr-Mo alloy conforming to ASTM F75	Cast Co-Cr-Mo alloy conforming to ASTM F75
Sizes	Sizes 1 to 10 standard, Left and Right Sizes 3-6 narrow, Left and Right Proportional Sizing	<u>Sigma:</u> CR Size 1.5, Left and Right (K961685) CR Sizes 2 – 6, Left and Right (K943462) CR150 Sizes 1.5 – 6, Left and Right (K082500) Constant Sizing <u>NexGen:</u> CR sizes A micro – H macro (K933785)
Fixation Surface	Cemented	Cemented

Characteristic	Attune™ Fixed Bearing Tibial Inserts	Sigma XLK Curved and PLI Tibial Inserts (K040166)
Material	AOX UHMWPE conforming to ASTM F648	XLK UHMWPE conforming to ASTM F648
Sizes	Proportional sizing CR inserts, sizes 1 to 10 Actual thicknesses 5, 6, 7, 8, 10, 12, 14, 16, and 18mm.	Constant sizing Curved and PLI inserts, sizes 1.5 to 6 Composite thicknesses 8, 10, 12.5, 15, 17.5, and 20mm.

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Characteristic	Attune™ Tibial Base	Sigma Co-Cr Tibial Trays (K032151)
Material	Cast Co-Cr-Mo alloy conforming to ASTM F75	Forged Co-Cr-Mo alloy conforming to ASTM F799
Sizes	Sizes 1 to 10	Sizes 1.5 to 6
Fixation Surface	Cemented	Cemented

Characteristic	Attune™ Patellae	Sigma 3-Peg Oval Patella (K961685, K950010)
Material	AOX UHMWPE conforming to ASTM F648	UHMWPE conforming to ASTM F648
Sizes	Sizes 29, 32, 35, 38, 41mm	Size 32 (K961685) Sizes 35, 38, 41 (K950010)
Fixation Surface	Cemented	Cemented

Summary of Substantial Equivalence:

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

Non-Clinical Testing:

Physical and mechanical testing was conducted on the AOX ultra high molecular weight polyethylene in accordance with ASTM F648. This testing includes the following characterization:

- Yield Strength
- Ultimate Tensile Strength
- Elongation to Break
- Young's Modulus
- Impact Resistance
- Fatigue Crack Propagation
- Compression Modulus
- Crystallinity (Differential Scanning Calorimetry)
- Peak Melting Temperature (Differential Scanning Calorimetry)
- Ash Content
- Gravimetric Swell Ratio
- Oxidation Index (Fourier Transform Infrared Spectroscopy)

- Effects of Accelerated Aging on Oxidation Index and Impact Resistance

The biocompatibility test plan developed to evaluate the AOX material was in accordance with the ISO draft Guidance on the Conduct of Biological Evaluation within a Risk Management Process (ISO/DTR 15499). Discussions of Risk Assessment with NAMSA provided additional guidance for establishing the series of biocompatibility tests to evaluate the AOX material. The test plan included methods that address FDA guidance documents and specifically ISO 10993 parts 3-6, 10, and 11. In addition to the ISO 10993 tests, other USP tests to characterize leachable components were conducted.

Functional testing was conducted in compliance with FDA guidance, Class II Special Controls Guidance Document: Knee Joint Patellofemoral and Femoral Tibial 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 and fatigue tests.

In vitro knee simulator wear testing provided in the submission demonstrated that the Attune CR femoral component/tibial insert couple exhibited a significant volumetric wear reduction as compared to a control total knee system. The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance.

Attune CR Fixed Bearing Wear Claim Information:

DePuy manufactured both the Attune CR fixed bearing total knee (subject) and the Sigma CR Curved fixed bearing total knee (control) in this wear test. All Attune CR products tested were size 5 while all Sigma CR products tested were size 3. The actual insert thicknesses used were 6mm for the Attune CR tibial AOX polyethylene insert (composite insert and base thickness of 10mm) and actual insert thickness of 8mm for the Sigma Curved tibial XLK polyethylene insert (composite insert and tray thickness of 10mm). The Attune CR inserts were manufactured from antioxidant stabilized compression molded GUR 1020 UHMWPE. The Sigma Curved inserts were manufactured from crosslinked (50 kGy) compression molded GUR 1020 UHMWPE. The Attune CR CoCr femoral and fixed bearing tibial base components were not sterilized for the tests. The Attune CR AOX fixed bearing inserts were sterilized and crosslinked via gamma radiation (75.0 – 90.0 kGy) and packaging (vacuum in foil pouch). The Sigma CR CoCr femoral and fixed bearing tibial tray components were sterilized via gamma radiation (28.5 kGy). The Sigma Curved XLK fixed bearing inserts were sterilized via gas plasma sterilization. Wear testing was performed via AMTI multi-axial displacement controlled knee joint simulator per ISO 14243-3 loads combined with published physiological kinematics at a frequency of 1 Hz for 5 million cycles utilizing a lubricant of 25% bovine serum with an average protein content of 16.5 mg/ml. The Attune mean gravimetric wear rate was 3.6 ± 0.3

mg/million cycles while the Sigma mean gravimetric wear rate was 7.12 ± 1.2 mg/million cycles. Thus the Attune CR fixed bearing total knee system exhibits 50% less overall mean gravimetric wear than the previously cleared DePuy Sigma Curved fixed bearing total knee system for the same composite thickness. The wear debris was analyzed at 1, 3, and 5 million cycles via LALLS and SEM analysis. The Attune AOX mean particle diameter (LALLS volume analysis), aspect ratio (SEM), roundness (SEM), and perimeter (SEM) measured 118.8um, 2.10, 0.56, and 3.56um while Sigma XLK measured 64.4um, 2.06, 0.56, and 3.17um respectively. No significant difference between the AOX and XLK debris samples was found. Wear testing to 10 million cycles was also performed utilizing the thinnest available insert thicknesses, actual insert thickness of 5mm for the Attune CR tibial AOX polyethylene insert (composite insert and base thickness of 9mm) and actual insert thickness of 6mm for the Sigma Curved tibial XLK polyethylene insert (composite insert and tray thickness of 8mm). The Attune mean gravimetric wear rate for the thin inserts was 5.4 ± 0.5 mg/million cycles while the Sigma mean gravimetric wear rate for the thin insert was 5.7 ± 0.7 mg/million cycles with no statistical difference in wear rate. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Clinical Testing:

None provided as it was not necessary to determine substantial equivalence between the Attune Knee System and the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Nancy Friddle
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DEC 10 2010

Re: K101433

Trade/Device Name: DePuy Attune™ 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: December 6, 2010

Received: December 7, 2010

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.

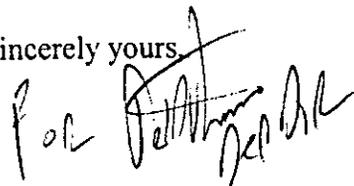
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

DEC 10 2010

2. INDICATIONS FOR USE

510(k) Number (if known): K101433

Device Name: DePuy Attune™ 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)

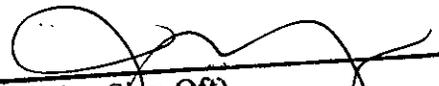
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for M. Melkersen

510(k) Number K101433