

K103756 #1/3

510(k) Summary

MAR 15 2011

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: December 2, 2010

Proprietary Name: DePuy Attune™ Total 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 Medialized Dome and Medialized Anatomic Patellae are substantially equivalent to currently marketed devices including:

- Sigma Patella (cleared as the Darwin Knee System), K950010
- PFC Cruciate Retaining Knee System, Size 1.5, K961685
- Attune Modified Dome Patella, K101433
- Kinemax Plus Patella, K910500
- Zimmer NexGen CR Knee System, K933785

Device Description: The Attune medialized dome and medialized anatomic 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 articular surface is offset medially proportional to the size of the component.

The Attune CR 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

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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 CR 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™ Total 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 table, the technological characteristics of the Attune medialized dome and medialized anatomic patellae are similar to the predicate devices including design and AOX material.

Characteristic	Attune Medialized Dome and Medialized Anatomic Patella (current submission)	Sigma 3-Peg Oval Patella (K961685, K950010) Attune Modified Dome Patella (K101433) NexGen Patella (K933785) Kinemax Plus Patella (K910500)
Material	AOX UHMWPE conforming to ASTM F648	Attune: AOX UHMWPE conforming to ASTM F648
Sizes	29, 32, 35, 38, 41 mm	Attune: 29, 32, 35, 38, 41mm Sigma: 32 (K961685) 35, 38, 41mm (K950010) NexGen: 29, 32, 35, 38, 41mm (standard sizes)
Articular Surface Offset	medial	Kinemax: medial
Fixation Surface	Cemented	Sigma: Cemented

Summary of Substantial Equivalence:

As part of the Attune CR total knee replacement system, the DePuy Attune medialized dome and medialized anatomic patellae are

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substantially equivalent to currently marketed devices as demonstrated with preclinical data.

Non-Clinical Testing:

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

Clinical Testing:

None provided as it was not necessary to determine substantial equivalence between the Attune Knee System's medialized dome and medialized anatomic patellae 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
Project Manager Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581

MAR 15 2011

Re: K103756

Trade/Device Name: DePuy Attune™ Total 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 22, 2010
Received: December 23, 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.

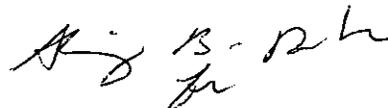
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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): K103756

Device Name: DePuy Attune™ Medialized Dome and Medialized Anatomic Patellae

Indications for Use:

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

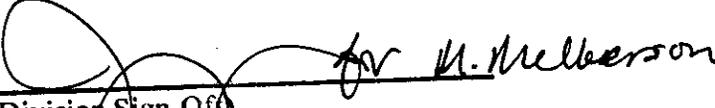
Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

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

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

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