DePuy Orthopaedics Incorporated  
Ms. Nancy Friddle  
Senior Project Manager, Regulatory Affairs  
700 Orthopaedic Drive  
Warsaw, Indiana 46581

Re: K140881  
Trade/Device Name: ATTUNE® Knee System-Cementless CR and PS Femoral Components  
Regulation Number: 21 CFR 888.3565  
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis  
Regulatory Class: Class II  
Product Code: MBH, JWH  
Dated: January 12, 2015  
Received: January 13, 2015

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 contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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
4. INDICATIONS FOR USE

510(k) Number (if known):  K140881

Device Name: ATTUNE® Knee System – Cementless CR and PS Femoral Components

Indications for Use:
The ATTUNE Cementless CR and PS Femoral Components are intended for cementless use within the ATTUNE 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 (provided that adequate bone is present).

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)
5. 510(K) SUMMARY

Summary of Safety and Effectiveness
ATTUNE Total Knee System – Cementless CR and PS Femoral Components
DePuy Orthopaedics, Inc.

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

Contact Person: Nancy Friddle, Sr. Project Manager, Regulatory Affairs

Date Prepared: April 4, 2014

Proprietary Name: ATTUNE® Knee System – Cementless CR and PS Femoral Components

Common Name: Total Knee Replacement Prosthesis

Classification Name: 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
21 CFR 888.3565 Knee joint patellofemorotibial polymer/metal porous coated uncemented prosthesis.

Product Code: JWH
MBH

Predicate Devices: The ATTUNE Cementless CR and PS Femoral Components, which are part of the DePuy ATTUNE Knee System, are substantially equivalent to currently marketed devices including:
- ATTUNE Knee System – CR Femoral Components, K101433
- ATTUNE Knee System – PS Femoral Components, K111433
- SIGMA CR Porocoat Femoral Components, K062654

Device Description: The ATTUNE Cementless cruciate retaining (CR) and 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 porous coated with Porocoat. The porous coated fixation surface comprises: the bone cut surfaces of the anterior flange, anterior chamfer, distal surface,
posterior chamfer, posterior condylar resection, as well as the lugs for additional stability. The fixation of the femoral component to the femoral bone is achieved by biologic fixation via ingrowth into the Porocoat porous coating. The ATTUNE femoral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75.

The ATTUNE Cementless CR Femoral Components are compatible with the ATTUNE CR Fixed Bearing inserts (K101433), fixed bearing tibial bases (K101433), and patellae (K103756).

The ATTUNE Cementless PS Femoral Components are compatible with the ATTUNE PS Fixed Bearing inserts (K111433), fixed bearing tibial bases (K101433), and patellae (K103756).

The ATTUNE CR Total Knee is designed to accommodate knee flexion to 150 degrees in those patients able to attain a high degree of knee flexion.

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 CR Total Knee is designed to accommodate knee flexion to 150 degrees in those patients able to attain a high degree of knee flexion.

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.

**Indications for Use:**
The ATTUNE Cementless CR and PS Femoral Components are intended for cementless use as the femoral components of the ATTUNE Knee 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 (provided that adequate bone is present).

**Technological Characteristics:**
As shown in the following tables, the technological characteristics of the ATTUNE Cementless CR and PS femoral components are similar to the predicate devices including design and material.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ATTUNE Cementless CR &amp; PS Femoral Components</th>
<th>ATTUNE (Cemented) CR Femoral Component (K101433)</th>
<th>ATTUNE (Cemented) PS Femoral Component (K111433)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Cast Co-Cr-Mo alloy conforming to ASTM F75</td>
<td>Cast Co-Cr-Mo alloy conforming to ASTM F75</td>
<td></td>
</tr>
<tr>
<td>Sizes</td>
<td>Sizes 1 to 10 standard, Left and Right</td>
<td>Sizes 1 to 10 standard, Left and Right</td>
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<tr>
<td></td>
<td>Sizes 3-6 narrow, Left and Right</td>
<td>Sizes 3-6 narrow, Left and Right</td>
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<tr>
<td></td>
<td>Proportional Sizing</td>
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<tr>
<td>Fixation Surface</td>
<td>Porocoat</td>
<td>Cemented</td>
<td></td>
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<td>Porocoat</td>
</tr>
</tbody>
</table>

**Summary of Substantial Equivalence:**

The ATTUNE Cementless CR and PS Femoral Components are identical in design to the ATTUNE CR and PS Femoral Components cleared for cemented use only in K101433 and K111433. The Porocoat porous coating of the ATTUNE Cementless CR and PS Femoral Components is identical to the Porocoat porous coating used on the SIGMA CR Porocoat Femoral Components cleared for Cementless use in K062654.
Non-Clinical Testing:
None provided as it was not necessary to determine substantial equivalence between the ATTUNE Cementless CR and PS Femoral Components and the predicate devices. As the coating for the subject device is identical to that in K062654, the characterization in K062654 also applies to this 510(k).

Clinical Testing:
None provided as it was not necessary to determine substantial equivalence between the ATTUNE Cementless CR and PS Femoral Components and the predicate devices.