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510(k) Summary

K102578 - Apex PS Knee ™ System 24 March, 2010

Submitter	OMNIlife science, Inc. 50 O'Connell Way E. Taunton MA 02718	**Contact**	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)
Preparation Date	24 March, 2010		
Device Name			
Trade Name	Apex PS Knee™ System		
Common/Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.		
Regulatory Class	Class II per 21 CFR §888.3560, §888.3565		
Product Code	JWH, MBH		
Legally Marketed Predicate Device(s)	• K060192- Apex Knee™ System- cleared 15Jul2006 • K073602- Apex Knee™ System Porous Coated Femoral Components(cementless), cleared 14Feb2008 • K950010- Darwin Knee System, cleared 15May1995 • K936159- The Natural-Knee® II knee system, cleared 22May2005		

Device Description

The APEX PS Knee System includes a posterior stabilized Femur Component incorporating a proportionally sized box. The Femur Component has the same bone cuts as the Apex Knee™ System (K060192) with the addition of a cut for the Femur Component box. Femur Components will be available in both cemented and uncemented versions. Size ranges, high flex, and all other design features of the Apex Knee System are retained. The PS Insert has a medio-lateral constraint and utilizes the Apex Knee System Tibial Baseplate. For each PS Insert, a range of UHMWPE thicknesses are available to aid in obtaining the proper soft tissue balance across the knee joint.

Indications for Use

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.

The Apex Knee™ Modular Tibia System Tibial Augment are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

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Predicate Device Comparison

Device Comparison				
	APEX PS TKA (Subject Device)	**APEX CR TKA (K060192, K073602)**	**Darwin Knee System (K950010)**	**Natural Knee II (K936159)**
Body Site	Knee	Knee	Knee	Knee
Intended use	Primary and revision 3 compartment TKA. Is intended for use as a primary or revision total knee replacement.	Primary and revision 3 compartment TKA. Is intended for use as a primary or revision total knee replacement.	Primary and revision 3 compartment TKA. Provides seamless transitions between primary and the most difficult revision cases.	Primary and revision 3 compartment TKA.
Patient Population	Skeletally mature patients.	Skeletally mature patients.	Skeletally mature patients.	Skeletally mature patients.
Similar Design and Specifications				
Femur Component	Femur Component: Identical to K060192-noncoated and K073602-coated	Femur Component: Coated and noncoated	Surface preparation for use with cement.	Femoral Component: CSTi™ titanium on CoCr porous coating
Tibial Baseplate/ Component	Tibial Component: Identical to K060192 -non coated	Tibial Component: Non-coated		Tibial Component: Titanium alloy
Asymmetric femur, anatomic patellar groove	Yes Designed with a deep, wide patellar groove	Identical Designed with a deep, wide patellar groove	Similar Deep single radius Trochlear groove, enables the patella to sit deeply in the groove even at high flexion angles.	Similar Deepened trochlear groove prevents excessive load on the patellar component while providing excellent range of motion.
Anatomic asymmetric tibial baseplate	Monobloc: Yes Modular: No	Monobloc: Yes Modular: No	No	Yes

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Condylar Box (cam) and Tibial Post (spine)	Rounded, open, and sloped box – Minimizes tibial spine edge loading and potential for polyethylene wear or tibial spine fracture.	Not Applicable, CR device	Squared box (cam)	Squared box (cam)
PS Insert	PS style insert with cam and post to control kinematics	N/A	PS style insert with cam and post to control kinematics	PS style insert with cam and post to control kinematics
PS Insert Post	Yes	No	Yes	Yes
High Flexion Design Option	Full flexion to 140°	Full flexion to 140°	Similar	Similar

Non-Clinical Test Summary

Apex PS Knee Flexion Range of Motion

- FDA -Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA (January 16, 2003)
- ASTM F2083-08- Standard Specification for Total Knee Prosthesis

Contact Area of the Apex PS Knee

- FDA -Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA (January 16, 2003)
- ASTM F2083-08- Standard Specification for Total Knee Prosthesis

Tibio-Femoral Constraint of the Apex PS Knee, PS Insert

- ASTM F2083-08- Standard Specification for Total Knee Prosthesis
- ASTM F1223-03- Standard Test Method for Determination of Total Knee Replacement Constraint

Apex Knee PS Tibial Insert Post Strength Testing

- FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA, issued on January 16, 2003

Apex PS Knee Patello-Femoral Contact Area and Stability

- ASTM F2083-08 Standard Specification for Total Knee Prosthesis
- FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA, issued on January 16, 2003

Apex PS Knee Lift-off Comparison to DePuy P.F.C. Sigma

Apex PS Knee Wear Review

- ISO 14243-3- Implants for surgery -- Wear of total knee-joint prostheses -- Part 3: Loading and displacement parameters for wear-testing machines with

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displacement control and corresponding environmental conditions for test.

- ISO 14243-2- Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement
- ASTM F1877- Standard Practice for Characterization of Particles

Apex PS Insert Minimum PS Thickness

- FDA Class II Special Controls Guidance Document (section 5)
- ISO 21536 (2007) - Non-active surgical implants -- Joint replacement implants -- Specific requirements for knee-joint replacement implants

Apex PS Knee Component Surface finish Review

- ISO 7207-2 (1998) - Components for partial and total knee joint prostheses -- Part 2: Articulating surfaces made of metal, ceramic and plastics materials
- ISO 21534 (2007)- Non-active surgical implants -- Joint replacement implants -- Particular requirements
- ISO 21536 (1998)- Non-active surgical implants -- Joint replacement implants -- Specific requirements for knee-joint replacement implants

Apex PS Knee Instrument Review

Apex PS Knee Tibio-Femoral Conformity Ratios

All samples tested met the acceptance criteria.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex PS Knee System is substantially equivalent to 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

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% Ms. Radhika Pondicherry
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East Taunton, Massachusetts 02718

MAR 25 2011

Re: K102578
Trade/Device Name: Apex 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: JWH, MBH
Dated: March 18, 2011
Received: March 21, 2011

Dear Ms. Pondicherry:

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,

for

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

Enclosure

Indications for Use

510(k) Number: K102578

Device Name: Apex PS Knee System

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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)

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

510(k) Number K102578