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K060192

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EXHIBIT A
510(K) SUMMARY

Apex Knee System

January 23, 2006

1. **Submitter:** OMNI life science™, Inc.
1390-A Decision Street
Vista, CA 92081

Contact: Ms. Christine Otis
Regulatory and Quality Systems
(760) 734-1550 x134 (voice)
(760) 734-1577 (fax)

2. Device Name

Proprietary Name:	Apex Knee System
Common Name:	Knee prosthesis, cemented
Classification Name:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Regulatory Class:	Class II per 21 CFR §888.3560

3. Intended Use

The Apex Knee System is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation and single use implantation. 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.

4. Device Description

The Apex Knee System is a primary or revision total knee replacement. This knee replacement is intended for use with bone cement and single use implantation. This knee system consists of a range of sizes of cobalt chrome femoral components with a deep patellar groove, dome shaped UHMWPE patella resurfacing components, UHMWPE tibial inserts, cobalt chrome tibial trays, and a titanium alloy bolt for locking the tibial insert to the tibial tray. This modular configuration allows the surgeon user to choose a combination of femoral and tibial tray component sizes to appropriately fit the anatomy of the patient, and to use a tibial insert with a size-for-size match to the femoral component. There are two different articular geometries for the tibial insert, a cruciate retaining ("CR") design, which allows retention of the posterior cruciate ligament, and an ultra-congruent posterior cruciate substituting ("Ultra") design. For each tibial insert, a range of UHMWPE thicknesses are available to aid in obtaining the proper soft tissue balance across the knee joint.

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5. Predicate Device Comparison

Substantial equivalence is claimed to the P.F.C.® Sigma Fixed Bearing Cruciate-Retaining knee system distributed by DePuy Orthopedics and the Natural-Knee® Cruciate Retaining and Posterior Stabilized knee system distributed by Zimmer, Inc. The following table summarizes the similarities and differences between the Apex Knee System and these predicate devices:

	Apex Knee	**P.F.C.® Sigma*** (K943462, K961685)	**Natural-Knee® II*** (K973412, K021578)
INTENDED USE			
Primary and revision, 3 compartment, cemented	Yes	Yes	Yes
DESIGN			
Porous coated	No	No	No
Asymmetric femur, anatomic patella groove	Yes	Yes	Yes
Anatomic (asymmetric) tibial tray	Yes	No	Yes
Metal-backed UHMWPE tibial component	Yes	Yes	Yes
Tibial insert designs	CR and Ultra	CR ("Curved")	CR ("Congruent") and Ultra ("Ultracongruent")
Tibial tray distal features	Central post and 2 keels	Central post and 2 short keels	Central post, 4 keels, and 4 pegs
Patella design	Round, single radius dome, 3 pegs	Round, single radius dome, 3 pegs	Round, partial dome, 3 pegs
MATERIALS			
Cobalt chrome femur	Yes	Yes	Yes
CoCr tibial tray	Yes	No – ti alloy	Yes
All-poly patella	Yes	Yes	Yes
UHMWPE	Sheet molded GUR 1020	Sheet molded GUR 1020	Sheet molded GUR 1020
Highly cross-linked UHMWPE (sterilization)	No (EtO)	No (γ irradiation in vacuum)	No (γ irradiation in nitrogen)

The most significant difference between these devices is that the Apex Knee employs UHMWPE tibial inserts that are fixed to the tibial tray using two parallel "dovetail" rails and a locking bolt, while the predicate devices employ UHMWPE inserts that are snap-fit into the tibial tray.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2006

OMNI life science, Inc.
% Edward J. Cheal, Ph.D.
Vice President of Research
175 Paramount Drive, Suite 302
Raynham, Massachusetts 02767

Re: K060192
Trade/Device Name: Apex 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
Dated: May 15, 2006
Received: May 16, 2006

Dear Dr. Cheal:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Apex Knee™ System

Indications For Use:

The Apex Knee System is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation and single use implantation. 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.

Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 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 General, Restorative, and Neurological Devices

510(k) Number