OMNI

AUG 2 5 2006

510(K) SUMMARY
K060072

Apex K1™ Hip Stem

April 13, 2006

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

Contact: Edward J. Cheal, Ph.D.
Vice President of Research
(760) 734-1550 x413

2. Device Name

Proprietary Name:	Apex K1™ Hip Stem
Common Name:	Hip prosthesis, uncemented
Classification Names:	Hip prosthesis, semi-constrained, metal/polymer, and hip joint metal/ceramic/polymer, uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3358 and §888.3353
Product Codes:	LPH and LZO

3. Intended Use

The Apex K1™ Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement. This femoral hip stem is intended for uncemented 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;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

4. Device Description

The Apex K1 Hip Stem consists of a rectangular tapered stem, and modular heads that connect to the tapered trunion on the neck. Four configurations are available for each size: standard and long lengths, each with standard and lateralized necks. These configurations allow the user to choose a combination of stem and head components to appropriately fit the anatomy of the patient. The Apex K1 Hip Stem may be used in conjunction with the Apex Modular™ Acetabular Cup (K031110) for total hip arthroplasty.

The femoral stems are manufactured from titanium alloy, and can be used with the cobalt chromium alloy heads and the alumina ceramic heads that are part of the Apex Modular and Apex K2 hip systems.

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5. Predicate Device Comparison

Substantial equivalence is claimed to the SL-Plus® and SLR-Plus® hip stems distributed by Plus Orthopedics (K001942 and K021178), and the Apex K2™ Hip System (K041950). The table below compares the features and characteristics of the Apex K1 Hip Stem to these predicate devices:

	Apex K1™ Hip Stem	**Apex K2™ Hip Stem** (K041950)	**SL-Plus® and SLR-Plus®** (K001942, K021178)
INTENDED USE			
Primary and revision hip replacement, non-cemented use	Yes	Yes	Yes
DESIGN			
Coated	Yes – plasma sprayed CP Ti	Yes – plasma sprayed CP Ti	No
Proximal coating (only)	Yes	Yes	NA
Modular head	Yes	Yes	Yes
Surface finish	Al-oxide grit blast	Al-oxide grit blast	Al-oxide grit blast
Modular neck	No	Yes	No
Tapered stem	Yes	Yes	Yes
Distal Cross-sectional shape	Rectangular	Rectangular	Rectangular
Distal slot(s)	No	No	No
Distal flutes	No	No	No
MATERIALS			
Titanium alloy stem	Yes (Ti-6Al-4V)	Yes (Ti-6Al-4V)	Yes (Ti-6Al-7Nb)
Cobalt chromium or alumina ceramic heads	Yes (both)	Yes (both)	Yes (both)
Titanium coating	Yes - unalloyed	Yes - unalloyed	No

The Apex K1 stem geometry is similar to the SL-Plus® and SLR-Plus® distributed by Plus Orthopedics. The most significant difference between these devices is that the Apex K2 stems employ modular necks (and heads), while the SL-Plus and SLR-Plus, and the subject device, have modular heads (only). Also the Apex K2 and Apex K1 stems have a plasma sprayed CP titanium coating on the proximal portion of the stem, whereas the SL-Plus and SLR-Plus stems are grit blasted with no plasma sprayed coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Edward J. Cheal
Vice President of Research
OMNI life science, Inc.
1390-A Decision Street
Vista, California 92081

Re: K060072
Trade/Device Name: Apex K1 Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO, LPH
Dated: August 21, 2006
Received: August 22, 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,

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): K060072

Device Name: Apex K1™ Hip Stem

Indications For Use:

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- Femoral neck and trochanteric fractures of the proximal femur.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060072