Apex Surgical™

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DEC 21 2004

510(K) SUMMARY

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Apex K2™ Hip Stem

July 19, 2004

1. **Submitter:** Apex Surgical, LLC
12 Harding Street
Suite 202
Lakeville, MA 02347

Contact: Edward J. Cheal, Ph.D.
Managing Director
(508) 947-6500 (voice)
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2. Device Name

Proprietary Name:	Apex K2™ Hip Stem
Common Name:	Hip prosthesis, uncemented
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3358

3. Intended Use

The Apex K2™ 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 K2™ Hip Stem consists of a rectangular tapered stem, modular necks that connect to the proximal end of the stem, and the modular heads that connect to the tapered trunion on the neck. This configuration allows the user to choose a combination of stem, neck, and head components to appropriately fit the anatomy of the patient. The various neck sizes allow for several length and lateral offset options for a given stem size. Several offset options are also available for the heads to allow further refinement of the lengths and offsets. The Apex K2 Hip Stem may be used in conjunction with the Apex Modular Acetabular Cup (K031110) for total hip arthroplasty.

The femoral stems (and modular necks) are manufactured from titanium alloy. The Apex K2 stems can be used with the cobalt chromium alloy heads and the alumina ceramic heads that are part of the Apex Modular hip system. The proximal metaphyseal region of each size femoral stem is circumferentially coated with unalloyed titanium applied by

plasma spray, the same coating method used by the predicate Apex Modular hip stem. As in the predicate Apex Modular stem, the alignment pin in the stem is manufactured from wrought cobalt chromium alloy.

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 Modular™ Hip System (K000788). The table below compares the features and characteristics of the Apex Modular™ Hip Stem to these predicate devices:

	Apex K2™ Hip Stem	**Apex Modular™** (K000788)	**SL-Plus® and SLR-Plus®** (K001942, K021178)
INTENDED USE			
Primary and revision hip replacement, non-cemented use	Yes	Yes	Yes
DESIGN			
Porous coated	Yes – plasma spray	Yes – plasma spray	No
Proximal coating (only)	Yes	Yes	NA
Modular head	Yes	Yes	Yes
Surface finish	Al-oxide grit blast	Ti grit blast	Al-oxide grit blast
Modular neck	Yes	Yes	No
Tapered stem	Yes	No	Yes
Distal Cross-sectional shape	Rectangular	Round	Rectangular
Distal slot(s)	No	Yes	No
Distal flutes	No	Yes – ridges	No
Proximal steps	No	Yes	No
MATERIALS			
Titanium alloy (Ti6Al4V) stem and neck	Yes	Yes	Yes
Cobalt chromium or alumina ceramic heads	Yes (both)	Yes (both)	Yes (both)
Titanium porous coating	Yes – unalloyed	Yes - unalloyed	No

The Apex K2 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 stem employs modular necks (and heads) similar to the Apex Modular™ hip system, whereas the SL-Plus and SLR-Plus stems have modular heads (only). Performance testing of the modularity was completed as per the relevant FDA guidance documents. Performance testing of the plasma sprayed unalloyed (CP) titanium coating was completed as per the relevant FDA guidance documents by APS Materials, Inc. and Bio-Coat, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Edward J. Cheal, Ph.D.
Managing Director
Apex Surgical, LLC
12 Harding Street, Suite 202
Lakeville, Massachusetts 02347

Re: K041950
Trade Name: Apex K2™Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: LPH
Dated: July 19, 2004
Received: July 20, 2004

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041950

Indications for Use

510(k) Number (if known): K041950

Device Name: Apex K2™ Hip Stem

Indications For Use:

The Apex K2™ Hip Stem is intended for use as the femoral component of a primary 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:

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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 K041950