Apex Surgical™

FEB 10 2005

510(K) SUMMARY

K 043123 p. 1/2

Apex Modular™ HA Hip Stem

November 3, 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)
(208) 248-8227 (fax)

2. Device Name

Proprietary Name:	Apex Modular™ HA 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 Modular™ HA 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 Modular™ HA Hip Stem consists of three modular components, with various sizes available for each component: the porous coated femoral stem, a modular neck that connects to the proximal end of the femoral stem, and a modular head that connects 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 Modular HA 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 Modular HA stems 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. The proximal metaphyseal region of each size femoral stem is circumferentially coated with unalloyed titanium applied by plasma spray, with an optional hydroxyapatite (HA)

coating on top of the titanium coating. 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 HA Mallory/Head® Porous Femoral Stem distributed by Biomet (K021403) and the Apex Modular™ Hip System (K000788). The table below compares the features and characteristics of the Apex Modular™ HA Hip Stem to these predicate devices:

	Apex Modular™ HA Hip Stem	**Apex Modular™** (K000788)	**HA Mallory/ Head® Porous Femoral Stem** (K021403)
INTENDED USE			
Primary and revision hip replacement, non-cemented use	Yes	Yes	Yes
DESIGN			
Porous coated	Yes – HA on plasma spray	Yes – plasma spray	Yes – HA on plasma spray
Proximal coating (only)	Yes	Yes	Yes
Modular head	Yes	Yes	Yes
Modular neck	Yes	Yes	No
Tapered stem	No	No	Yes
Distal Cross-sectional shape	Round	Round	Round
Distal slot(s)	Yes	Yes	No
Distal flutes	Yes - ridges	Yes – ridges	No
Proximal stabilization	Horizontal steps	Horizontal steps	Fins
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	Yes - unalloyed
Hydroxyapatite coating	Yes	No	Yes

The stem design is the same as the predicate Apex Modular stem, updated to share modular heads and necks with the Apex K2 hip stem (K041950). The plasma spray titanium coating is identical to the plasma spray coating on the Apex Modular and K2 stems, with the addition of the option of a plasma sprayed hydroxyapatite (HA) coating on top of the plasma sprayed titanium; this coating is similar to the predicate HA Mallory/Head femoral stem. The most significant difference between these devices is that the Apex Modular HA stem employs modular necks (and heads) similar to the Apex Modular™ hip system, whereas the HA Mallory/Head stems have modular heads (only).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K043123
Trade/Device Name: Apex Modular™ HA Hip Stem
Regulation Number: 21 CFR 888.3358 and 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, MEH
Dated: November 3, 2004
Received: November 12, 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.

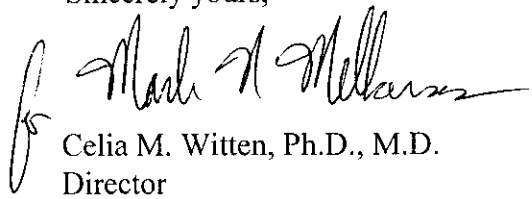
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K043123

Device Name: Apex Modular™ HA Hip Stem

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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)

Mark N Melkerson

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

510(k) Number K043123