MAY 22 2003

Apex Surgical™

510(K) SUMMARY

K031110

Apex Modular™ Acetabular Cup

May 12, 2003

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™ Acetabular Cup
Common Name:	Acetabular cup, 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™ Acetabular Cup is intended for use in combination with the Apex Modular Hip Stem in total hip replacement procedures. This acetabular cup is intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. This prosthesis is intended for single use implantation, and 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™ Acetabular Cups are manufactured of titanium alloy, with a sintered bead porous coating (commercially pure titanium, irregular bead geometry). The liners are manufactured of ram extruded ultrahigh molecular weight polyethylene, sterilized using ethylene oxide. The articular geometry of the liners are compatible with existing Apex Modular femoral heads, manufactured from cobalt chrome or ceramic, 28 or 32 mm diameter, with various offsets.

5. Predicate Device Comparison

Substantial equivalence is claimed to the DePuy Pinnacle™ Acetabular Cup and the Wright Medical Lineage™ Acetabular cup. The table below compares the features and characteristics of the Apex Modular Acetabular Cup to these predicate devices.

	Apex Modular™ Acetabular Cup	**DePuy Pinnacle™ Acetabular Cup** (K000306 and K001534)	**Wright Medical Lineage Acetabular Cup** (K002149)
INTENDED USE			
Primary and revision total hip replacement	Yes, cementless	Yes, cementless	Yes, cementless
DESIGN			
Liner engagement	19° taper with PE locking ring	"VIP Taper" with PE locking ring	19° taper with PE locking ring
Minimum PE thickness	6 mm	6 mm	>4 mm
Liner options	Neutral, and 15° hooded	Neutral, 4 mm lateralized, 10° angled, and 15° hooded	Neutral, 4 mm lateralized, and 15° hooded
Shell options	No hole and three hole (plus apical hole)	No hole, three hole, spiked, and multihole (8-12 holes), plus apical hole (all)	No hole and three hole (plus apical hole)
Head diameters	28 and 32 mm	28, 32, and 36 mm	22.25, 28 and 32 mm
Shell profile	Full profile, 14° rim flare	Full profile, hemispherical	Full profile, 14° rim flare
MATERIALS			
Liner	UHMWPE (ram extruded, ETO sterilized)	UHMWPE (ram extruded, radiation cross-linked, gas plasma sterilized)	UHMWPE (ram extruded, ETO sterilized)
Shell	Titanium alloy	Ti alloy	Ti alloy
Porous coating	CP titanium sintered beads	CP titanium sintered beads	CP titanium sintered beads

These cups use similar materials, porous coatings, design options, and liner locking mechanisms. Liner retention studies were performed on the Apex Modular liners as per the relevant FDA guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

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

Re: K031110
Trade/Device Name: Apex Modular™ Acetabular Cup
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: April 4, 2003
Received: April 8, 2003

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.

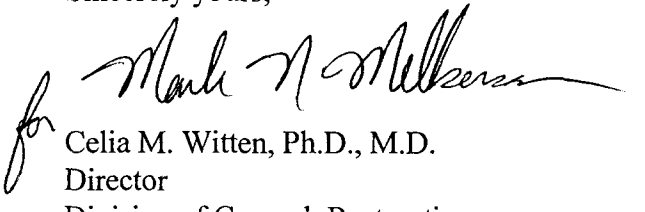
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



for 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

Device Name: **Apex Modular™ Acetabular Cup**

K 031110

The Apex Modular™ Acetabular Cup is intended for use in combination with the Apex Modular Hip Stem in total hip replacement procedures. This acetabular cup is intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

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- Femoral neck and trochanteric fractures of the proximal femur.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhaus

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

510(k) Number K031110

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)