Apex Surgical™

NOV 2 7 2001

510(K) SUMMARY

K 012918

Apex Modular™ Alumina Femoral Head

August 27, 2000

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™ Alumina Femoral Head
Common Name:	Ceramic femoral head
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3353

3. Intended Use

The Apex Modular™ Alumina Femoral Head is intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup component. 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™ Alumina Heads are manufactured of Biolox® *forte* alumina (high purity aluminum oxide ceramic) by CeramTec AG (Biolox® is a registered trademark of CeramTec AG). The bore on this ball was designed and tested for compatibility with the neck taper on the Apex Modular Hip Stem (K000788). These modular heads are available in 28 mm and 32 mm diameters, with three offset options for each head size: -3.5, 0, and +3.5 mm (28 mm diameter heads) and –4, 0, and +4 mm (32 mm diameter heads).

5. Predicate Device Comparison

Substantial equivalence is claimed to the Smith & Nephew Biolox Alumina Ceramic Heads and the Plus Orthopedics Biolox® *forte* Alumina Ceramic Heads. The table below compares the features and characteristics of the Apex Modular Alumina Femoral Head to these predicate devices.

	Apex Modular™ Alumina Femoral Head	**Smith & Nephew Biolox Alumina Ceramic Heads** (K981847 and K991162)	**Plus Orthopedics Biolox® *forte* Alumina Heads** (K990261)
INTENDED USE			
Primary and revision total hip replacement	Yes	Yes	Yes
DESIGN			
Taper design	12/14	12/14	12/14
Head diameters	28 and 32 mm	28 and 32 mm	28 and 32 mm
Offsets, 28 mm heads Offsets, 32 mm heads	-3.5, 0, +3.5 mm -4, 0, +4 mm	0, +3.5, +7 mm 0, +4, +8 mm	-3.5, 0, +3.5 mm -4, 0, +4 mm
MATERIALS			
Ceramic head	Alumina	Alumina	Alumina
Stem trunion	Titanium alloy	Ti alloy or CoCr	Ti alloy or CoCr

These predicate heads are produced by the same vendor (CeramTec AG), using the same material (Biolox® *forte*), as the subject device. Burst and fatigue testing of these alumina heads on the Apex Modular 12/14 taper have been completed as per the relevant FDA guidance document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

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

Re: K012918
Trade/Device Name: Apex Modular Alumina Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: August 27, 2001
Received: August 30, 2001

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.

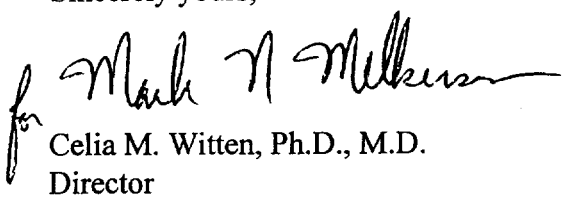
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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™ Alumina Femoral Head**

K012918

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- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K012918

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)