MAR 2 0 2001

Apex Surgical™

510(K) SUMMARY

K 003923

Apex Modular™ Zirconia Femoral Head

December 18, 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™ Zirconia 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™ Zirconia 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™ Zirconia Heads are manufactured of PROZYR® zirconia (yttrium stabilized zirconium oxide ceramic) by Saint-Gobain Advanced Ceramics Desmarquest. 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 diameter (only) with four offset options: -3.5, 0, +3.5, and +7 mm.

5. Predicate Device Comparison

Substantial equivalence is claimed to the S-ROM® Zirconia Ceramic Femoral Head and the Biomet Zirconia Ceramic Modular Head. The table below compares the features and characteristics of the Apex Modular Zirconia Femoral Head to these predicate devices.

	Apex Modular™ Zirconia Femoral Head	**S-ROM® Zirconia Ceramic Femoral Head** (K973307)	**Biomet Zirconia Ceramic Modular Head** (K915641 and K943586)
INTENDED USE			
Primary and revision total hip replacement	Yes	Yes	Yes
DESIGN			
Taper design	12/14	11/13	Type I and Type II
Head diameters	28 mm	26, 28, and 32 mm	28 and 32 mm
Offsets (on 28 mm)	-3.5, 0, +3.5, and +7 mm	0 and +6 mm	-5, -3, 0, +3 mm
MATERIALS			
Ceramic head	Zirconia	Zirconia	Zirconia
Stem trunion	Titanium alloy	Titanium alloy	Ti alloy or CoCr

The two most significant differences between the present device and these two predicate devices are the trunion specifications and the specific offset (neck length) options. Burst testing and a finite element design analysis for the specific 12/14 taper, including all four offset options, 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

MAR 2 0 2001

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

Re: K003923
Trade Name: Apex Modular™ Zirconia Femoral Head
Regulatory Class: Class II
Product Code: LZO
Dated: December 18, 2000
Received: December 20, 2000

Dear Dr. Cheal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

Enclosure

Indications For Use

Device Name: **Apex Modular™ Zirconia Femoral Head**

K 003923

The Apex Modular™ Zirconia 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.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K003923

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)