DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Michael C. Wall, RN
Official Correspondent
Whiteside Biomechanics
12634 Olive Boulevard
St. Louis, Missouri 63141

JUL 30 1997

Re: K971721
Whiteside Biomechanics Zirconia Ceramic Femoral Head
(Sizes 22mm 0, 22mm +3.5, 26mm -3.5)
Regulatory Class: II
Product Code: LZO
Dated: May 8, 1997
Received: May 9, 1997

Dear Mr. Wall:

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 and the following limitation that the package insert must reflect that the Whiteside Biomechanics Zirconia Ceramic Femoral Head is to only be used with the Whiteside Biomechanics 12/14 taper made from wrought titanium alloy. This information must be identified in the package insert.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

JUL 30 1997

510(k) Summary

K971721

Device:

Classification Name:	prosthesis, hip semiconstrained,metal, polymer, porous, uncemented
Classification No.:	87LZO
Common/Usual Name:	zirconia ceramic femoral head
Proprietary Name:	Whiteside Biomechanics,Inc. Zirconia Ceramic Femoral Head

Manufacturer Identification:

Whiteside Biomechanics, Inc.
12634 Olive Blvd.
Creve Coeur, MO 63141

Establishment Registration Number: 1932213

Device Description:

The Whiteside Biomechanics, Inc. Zirconia Ceramic Femoral Head will consist of a generally spherical, partially hollow (trunnion bore) ceramic ball. The implant will have a machined flat on the most distal surface with the trunnion centered and machined proximally into its center. The bore will be a Whiteside Biomechanics 12/14 taper intended to be seated on a trunnion compatible with this taper (see warning label). The head's outer perimeter is intended to articulate with a polyethylene acetabular component of compatible size. Labeling on the femoral head will be printed on a beveled surface machined around the periphery of the trunnion bore or on the top-inside flat of the bore.

Intended Use:

This device is intended to be used for:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. rheumatoid arthritis
3. correction of functional deformity
4. revision procedures where other treatments or devices have failed
5. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
6. treatment of osteomyelitis
7. endoprosthesis femoral osteotomy

Additional Information:

This femoral head is made from magnesia stabilized zirconia ceramic. The device will be sterilized with 100% ethylene oxide in nitrogen according to the AAMI guidelines for sterilization. Resterilization of femoral heads upon contamination is not recommended. DO NOT RESTERILIZE.

(1) faxed 7-17-97

510(k) Number (if known): K971721

Device Name: Whiteside Biomechanics Inc. Zirconia Ceramic Femoral Head

Indications For Use:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2. rheumatoid arthritis,
3. correction of functional deformity,
4. revision procedures where other treatments or devices have failed,
5. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques,
6. treatment of osteomyclitis,
7. endoprosthesis femoral osteotomy.
8. use with a polyethylene cup with or without metal backed shell.

(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 Devices
510(k) Number K971721

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)