AUG 21 1998

K981238

510(k) SUMMARY

Device:

Classification Name:	Prosthesis, Hip, Hemi-, Femoral, Metal / Polymer, Cemented or Uncemented
Classification No.:	87KWY
Common / Usual Name:	Bipolar femoral head
Proprietary Name:	Whiteside Biomechanics, Inc. Bipolar Femoral Head

Manufacturer Identification:

Whiteside Biomechanics, Inc.
12634 Olive Blvd.
St. Louis, MO 63141

Establishment Registration Number: 1932213

Device Description:

A bipolar head which is preassembled. Outer head is made from Cobalt Chrome alloy ASTM F75 and sizes range from 38mm to 62mm in 1mm increments. An UHMW polyethylene insert will be pressed into the inner surface of the outer head during the manufacturing process. This polyethylene insert will articulate with an inner femoral head. The inner head diameter will be 22mm for outer head diameters from 38mm to 55mm and 26mm for outer diameters from 56mm to 62mm. The inner head will be pressed into the poly insert in the operating room using a bipolar head assembly device.

Intended Use:

This device is intended to be used for :

1. femoral 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, and
5. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Additional Information:

This femoral head is made of Cobalt Chrome with a UHMW poly insert. The inner head will be pressed into the polyethylene insert in the OR. This femoral head will be sterilized by 100% ethylene oxide in nitrogen according to the AAMI Guidelines for sterilization. Resterilization is NOT recommended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1998

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

Re: K981238
Trade Name: Bipolar Femoral Head
Regulatory Class: II
Product Code: KWY
Dated: June 29, 1998
Received: July 23, 1998

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. 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 (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

510(k) Number (if known): K981238

Device Name: Whiteside Biomechanics, Inc. Bipolar Femoral Head

Indications For Use:

1. Noninflammatory degenerative joint disease including osteoarthritis.
2. Avascular necrosis.
3. Correction of functional deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of femoral neck and trochanteric fractures of the proximal femur with head involvement and non-union of femoral neck fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ yes (Per 21 CFR 801.109) OR Over-The-Counter Use No

(Optional Format 1-2-96)

Russell T. Ryan

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981238