MAY 0 3 2002

K012800

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Section 4: **510(k) Summary**

Submitter Name/Address:	Whiteside Biomechanics, Inc. 12634 Olive Blvd. St. Louis, MO 63141 P: 314-996-8540 F: 314-996-8543
Establishment Registration #:	1932213
Correspondent:	George Palfi
Device Name:	Symmetric Unicompartmental Knee System
Proprietary Name:	Whiteside Biomechanics, Inc. Symmetric Unicompartmental Knee System
Common Name:	Unicompartmental Knee System
Classification Name:	Knee joint femorotibial, metal/polymer, semi-constrained, cemented prosthesis.
Classification Panel:	Class II
Substantial Equivalence To:	Natural-Knee II Unicompartmental Knee (K955778)

Device Description:

The Symmetric Unicompartmental Knee System is intended for the resurfacing of one side of the knee joint. The system consists of metallic femoral and tibial components and a polyethylene tibial insert.

The FEMORAL COMPONENT is symmetrically designed eliminating the need for left/right orientations. The femoral component is manufactured from cast cobalt chromium/molybdenum (CoCrMo) and features a central peg, which aids in stabilization. A central strut is provided for rotational stability and added strength. The femoral component will be available in five sizes (1-5) and will be porous coated with Commercial Pure Titanium (CPTi).

The TIBIAL COMPONENT is a symmetrically designed component, eliminating the need for left/right orientations. The tibial component is manufactured from wrought titanium alloy (Ti-6Al-4V). The tibial tray features a central fin and four pegs on the underside aiding in rotational stabilization. A screw hole is in the center of the tibial

tray for optional screw fixation. The tibial tray is designed with locking features permitting the UHMWPE tibial insert to be snapped into place. The tibial tray has 5 sizes (1 – 5) and is porous coated with Commercial Pure Titanium (CPTi).

The TIBIAL INSERT is also a symmetrically designed component manufactured from Ultra-High Molecular Weight Polyethylene (ASTM F648). The inserts' articulating geometry is semi-constrained and is captured in the tibial tray by the mating capture features. The insert is available in 5 thicknesses (6, 8, 10, 12, and 14mm) and 5 sizes (1 – 5).

Push-out strength test results on the tibial tray insert are comparable to other legally marketed devices.

The Symmetric Unicompartmental Knee System is also similar to the Howmedica PCA Unicompartmental Knee System, the Johnson & Johnson PFC Unicompartmental Knee System, and the Smith & Nephew Genesis Unicompartmental Knee.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Mr. George Palfi
General Manager
Whiteside Biomechanics, Inc.
12634 Olive Boulevard
St. Louis, Missouri 63141

Re: K012800
Trade/Device Name: Symmetric Unicompartmental Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial, metal/polymer, semi-constrained, cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: February 14, 2002
Received: February 15, 2002

Dear Mr. Palfi:

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 Mark N Melkerson

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

510(K) Number (if known): K012800

Device Name: Symmetric Unicompartmental Knee System

Indications For Use:

The Symmetric Unicompartmental Knee System is for Cemented Use Only and is indicated for restroing either compartment of a knee that has been damaged by rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, failed osteotomies or hemiarthroplasties.

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

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 K012800