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K033313

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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:	Amy Cranmer
Device Name:	Quatro-M Femoral Component
Proprietary Name:	Whiteside Biomechanics, Inc. Quatro-M Femoral Component
Common Name:	Quatro-M
Classification Name:	Prosthesis, hip, semi-constrained, metal/polymer, uncemented (LWJ); Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (LPH); and Prosthesis, hip, semi-constrained, metal/ceramic/polymer cemented or non-porous uncemented (LZO)
Classification Panel:	Class II
Substantial Equivalence To:	Quatroloc Plasma Spray Femoral Component (K964616)

Device Description:
The implant will consist of a solid, rectangularly cross-sectioned wrought titanium 6AL-4V (ASTM 1472) stem with tapered proximal end and is intended to seat a conventional modular spherical head. The device is intended to articulate with a conventional acetabular implant of the surgeon's choice. The distal portion will be a smooth taper anterior-posteriorly and medial – laterally with a grit blasted distal surfaces. The proximal stem will be porous coated with commercially pure titanium plasma spray on all proximal surfaces excluding the articular interface trunion.

The femoral component is made of wrought titanium 6A1-4V (ASTM F1472). The proximal portion of the stem will be porous coated on all surfaces, excluding the ball trunion. The distal portion of the stem will be grit blasted. Sterilization will be 100% ethylene oxide and nitrogen in accordance with AAMI guidelines for sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2004

Ms. Amy Cranmer
Official Correspondent
Whiteside Biomechanics, Inc.
12634 Olive Boulevard
St. Louis, Missouri 63141

Re: K033313
Trade/Device Name: Quatro-M Plasma Spray Femoral Component
Regulation Number: 21 CFR 888.3350; 21 CFR 888.3358; 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: II
Product Code: LWJ, LPH, LZO
Dated: July 8, 2004
Received: July 8, 2004

Dear Ms. Cranmer:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 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

510(k) Number (if known): K033313

Device Name: Quatro-M Plasma Spray Femoral Component

Indications for Use:

The Quatro-M Plasma Spray Femoral Component is for press-fit, uncemented use. It is intended to be used for:

1. Noninflammatory degenerative joint disease including osteoarthritis
2. Rheumatoid arthritis
3. Avascular necrosis
4. Correction of functional deformity
5. Revision procedures where other treatments or devices have failed
6. Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

Prescription Use: Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millerson

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

510(k) Number K033313