

JUL 23 1997

510(k) SUMMARY

K971718

Device:

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| Classification Name: | Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous Uncemented |
| Classification No.: | 87LPH |
| Common/Usual Name: | Acetabular Shell |
| Proprietary Name: | Micro-Seal Acetabular System |

Manufacturer Identification:

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

Establishment Registration Number: 1932213

Device Description:

This implantable device consists of a generally hemispherical shape titanium shell with six screw holes for optional additional fixation with bone screws. A UHMWPE modular liner is pressed or tapped into the shell. Push out resistance of the polyethylene is attained by the interlocking geometry of the shell. Rotational fixation is obtained by tabs located on the liner that mate with notches on the shell. Toggle fixation is achieved with the nub on the backside of the liner fitting into the driver hole through the shell. The inner surface of the polyethylene articulates with the spherical portion of the femoral component.

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.

Additional Information:

The acetabular shell is made of titanium 6Al-4V (ASTM F1472) with commercially pure titanium plasma spray (ASTM F1580). The liner is made of UHMWPE conforming to ASTM F648. The device is supplied double peel packed and EtO sterilized in accordance with AAMI Guidelines for sterilization (ISO 11135).

I. Sterilization Controls

Sterilization Statement

All acetabular components will be provided sterile and double pouched. They will be sterilized in 100% ethylene oxide with nitrogen. The box labels will include an exposure indication dot that will change color upon exposure to the sterilant. Through testing methods established by applicable sections of AAMI, FDA, NRC, and ISO guidelines for sterilization validation, the devices packaged and sterilized will meet 10^{-6} sterility level. Whiteside Biomechanics, Inc. will make NO claim to "pyrogen free" status.

We will use: Tri-State Hospital Supply Corporation, 301 Catrell, Howell, Michigan 48843 (517) 546-5400 for sterilization.

We appreciate your review of this information and attachments, and look forward to your reply. If you have any questions, or require points of clarification, please call me at (314) 996-8540 and I would be happy to help facilitate this process.

Sincerely,



Michael C. Wall
Official Correspondent

Enclosures



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 23 1997

Re: K971718
Whiteside Biomechanics Micro-Seal Acetabular
System with Plasma-Spray Titanium Coating
Regulatory Class: II
Product Code: LPH
Dated: May 6, 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. 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.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(C) the device cleared for marketing by this letter as requiring postmarket surveillance. The rationale for this decision is contained in the enclosed attachment.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Room 3083 (HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket

surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

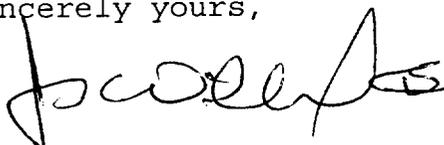
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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

Enclosures

510(k) Number (if known): K971718

Device Name: MicroSeal Plasma Sprayed Acetabular Shell

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,

(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 K971718

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

SK-45