

510(k) Summary

K972361

Proprietary Name: V40 Zirconia Femoral Heads

Common Name: Ceramic Femoral Head

Classification Name and Reference: 21 CFR 888.3353

This device is a component of a hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Proposed Regulatory Class: Class II

Device Product Code: OR(87) LZ0

For information contact:

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Manager, Regulatory Affairs
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Date Summary Prepared: 6/24/97

This device is a modular femoral head component which is affixed to a femoral stem component and articulates with a polyethylene acetabular cup or a metal backed polyethylene acetabular cup to reconstruct painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, subcapital fracture or a revision of a failed femoral prosthesis. The Zirconia Femoral Heads described in this submission are a modification of a previously cleared Zirconia head (K952418). The modification is a change in the supplier of the device and the introduction of additional sizes.

The substantial equivalence is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to several devices currently in commercial distribution including: Howmedica® V40 Zirconia Femoral Head (K952418) and Howmedica® 32mm Zirconia Femoral Head (2° 52') (K920577).

All of the named devices are intended to be used as the modular femoral head component of a total hip replacement. The basic design of these devices is generally the same, with varying diameters and lengths of internal tapers to accommodate individual patient needs. The material used in the manufacture of these heads is also the same.

Assembly of all the named femoral head components to an appropriate femoral stem component requires similar instrumentation and preparation. All of the named V40 Zirconia heads are intended to articulate with the femoral components of the previously released Partnership Total Hip System. Relative indications and contraindications for all of the zirconia heads named are the same.

Testing of the V40 Zirconia Femoral Heads included ultimate compression strength and axial distraction. All heads tested for ultimate compression strength failed at loads higher than 46 kN as specified in the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1997

Mr. Frank Maas
Manager, Regulatory Affairs
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Pfizer Hospital Products Group
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Re: K972361
V40 Zirconia Femoral Heads
Regulatory Class: II
Product Code: LZ0
Dated: June 24, 1997
Received: June 25, 1997

Dear Mr. Maas:

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 V40 Zirconia Ceramic Femoral Heads are to be used only with Howmedica® Partnership Hip System with 5° 40' taper trunnions.

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

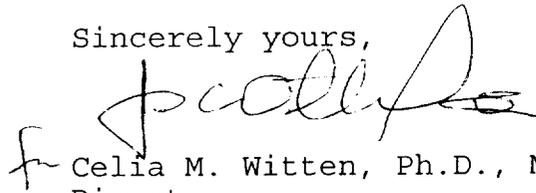
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comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect 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,


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

Indications for Use

510(k) Number (if known): K972361

Device Name: V40 Zirconia Femoral Heads

Indications for Use:

The V40 Zirconia Femoral Heads are intended to be used with modular femoral components in primary and secondary cemented or cementless total hip replacement procedures. These devices are intended to articulate with a polyethylene cup or a metal backed polyethylene cup component to reconstruct painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, subcapital fracture, or a revision of a failed femoral prosthesis.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972361

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)