510(k) Summary

Alumina V40™ Femoral Heads

Proprietary Name:	Alumina V40™ Femoral Heads
Common Name:	Artificial Hip Component Classification Name and Reference: Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Nonporous Uncemented Prosthesis, 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Device Product Code:	87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/ Ceramic /Polymer, Cemented or Non-Porous, Uncemented
Predicate Proprietary Name:	Alumina V40™ Femoral Heads
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 LZO
For Information contact:	Debra Bing Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5413 Fax: (201) 831-6038

Description/Technological Comparison

The subject Alumina V40™ Femoral Heads and the predicate Alumina V40™ Femoral Heads (#K003413) are manufactured from the same materials using the same manufacturing processes. They share the same indications for use and are of nearly identical design. The subject Alumina V40™ Femoral Heads differ from the predicate Alumina V40™ Femoral Heads as follows:

1. An improved taper grinding technique provides a smoother taper surface finish. This smoother taper surface finish yields stronger ball heads that can now be used with Orthinox™ stainless steel stems (in addition to the titanium alloy stems previously cleared for use with the predicate femoral heads).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2003

Ms. Debra Bing
Regulatory Affairs Manager
Stryker Homedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K023901
Trade Name: Alumina V40™ Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Nonporous Uncemented Prosthesis
Regulatory Class: II
Product Code: *LZO*
Dated: November 21, 2002
Received: November 22, 2002

Dear Ms. Bing:

We have reviewed your Section 510(k) premarket 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) 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.

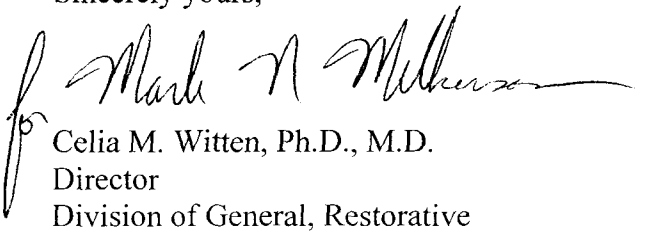
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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): K023901

Device Name: Alumina V40™ Femoral Heads

The subject femoral head is a single-use device intended for use in total hip replacement. It is intended for use with any currently available Howmedica Osteonics acetabular component. It is intended for use with any currently available Howmedica Osteonics hip stem featuring the V40™ trunnion **and** manufactured from a titanium alloy or Orthinox™ Stainless Steel. It is not intended for use with any stem manufactured from cobalt chromium alloy.

Indications:

- Painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant);
- Rheumatoid arthritis;
- Correction of functional deformity;
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum;
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable uing other techniques;
- Revision procedures where other treatments or devices have failed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Mark N Milhous

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

K023901