

K965002

Summary of Safety and Effectiveness

JUN 27 1997

Encore Orthopedics™, Inc.  
8900 Shoal Creek  
Bldg. 300  
Austin, TX 78757  
512-795-8696  
Ashley M. Bock

Trade Name: Zirconia ceramic heads for use with Encore® Vitality™, SL and SLR PLUS, and Foundation™ Forged, Textured and Porous Stems.

Common Name: Ceramic femoral head

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented prosthesis per 21 CFR 888.3353, (LZO).

Description: Zirconia ceramic heads for use with Foundation® Forged (K952191), Textured (K935263) and Porous Stems (K952297), the Encore® Vitality™ Stem (K962560) and the SL and SLR PLUS (K932481) Hip Stems which have been cleared for commercial distribution.

Indications for Use: The indications for use of the total hip replacement prosthesis include: degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques.

Comparable Features to Predicate Device(s): The Zirconia ceramic heads to be used with Foundation® Forged, Textured and Porous Stems, the Encore® Vitality™ Stem and SL and SLR PLUS Hip Stems are equivalent in material, design and clinical indications to the zirconia heads also manufactured by Demarquest for Zimmer (K944601), DuPuy (K926395), and Smith and Nephew Richards, Inc. (K935921).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Ashley M. Bock  
Regulatory Specialist  
Encore Orthopedics, Inc.  
9800 Metric Boulevard  
Austin, Texas 78758

JUN 27 1997

Re: K965002  
Zirconia Ceramic Femoral Heads for use with the  
Foundation Forged, Textured, and Porous Stems, the  
Encore Vitality Stem, and SL and SLR PLUS Hip Stems  
Regulatory Class: II  
Product Code: LZ0  
Dated: April 15, 1997  
Received: April 17, 1997

Dear Ms. Bock:

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 Zirconia Ceramic Femoral Heads for use with the Foundation Forged, Textured, and Porous Stems, the Encore Vitality Stem, and SL and SLR PLUS Hip Stems are to be used only with cobalt-chrome and Ti6Al4V alloy hip stems with the Cerasiv 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 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

Page 3 - Ms. Ashley M. Bock

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, -

*Marie A. Schroeder, MS, PT*

*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

Enclosure

510(k) Number (if known): K965002

Device Name: Encore Zirconia Femoral Heads

Indications For Use:

**Encore® Zirconia Heads**  
**Indications For Use**

The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is 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)

*Mario A. Schroeder for Mueller*

(Division Sign-Off)

Director of General Restorative Devices

510(k) number K965002

Prescription Use X  
(per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)\_