

AUG 12 1999

Summary of Safety and Effectiveness

K992109

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: Encore Fully Coated Hip Stem

Common Name: Cementless hip stem

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

Description: The Encore Fully Coated Hip Stem is available in a variety of proximal body, head offset and distal stem diameter and length configurations. When viewed in the mediolateral plane the Encore Fully Coated Hip Stem tapers slightly proximal to distal in the body area only. The proximal body is trapezoidal in cross-sectional geometry and tapers lateral to medial. The distal stem portion is cylindrical and the larger sizes have anterior/posterior flutes to decrease the distal stem stiffness.

The Encore Fully Coated Hip Stem is fabricated from cast CoCrMo that conforms to ASTM F75. The outside surface of the stem is porous coated with CoCrMo beads (ASTM F75) to provide a porous surface for enhanced fixation. The stem is intended to be press-fit.

The Encore Fully Coated Hip Stem is collared and has a Morse type taper to receive modular heads. This stem is available with a standard head/stem offset and an enhanced offset version that provides additional lateralization of the patient's femur without increasing leg length. The stem/neck angle is 135°.

Intended Use: The Encore Fully Coated Hip Stem is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty where bone loss is minimal.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include cast CoCrMo substrate, straight stem, symmetric, collar, basic shape, and modular heads.

Test Results: Laboratory testing and finite element analysis was used to determine the fatigue stem strength and Morse type taper was conducted.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Ms. Debbie De Los Santos
Regulatory and Clinical Specialist
Encore Orthopedics, Incorporated
9800 Metric Boulevard
Austin, Texas 78758

Re: K992109
Trade Name: Encore Fully Coated Hip Stem
Regulatory Class: II
Product Code: LPH and LZO
Dated: June 21, 1999
Received: June 22, 1999

Dear Ms. De Los Santos:

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

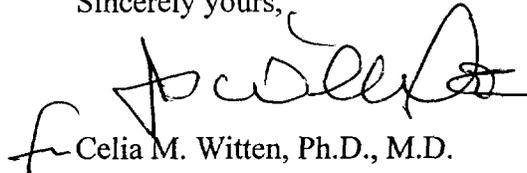
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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. 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 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K992109

Device Name: Encore Fully Coated Hip Stem

Indications For Use:

Encore Fully Coated Hip Stem
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. This stem is to be press-fit.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992109