6/1/99

K991227

510(k) Summary of Safety and Effectiveness

(1)	**Submitter's name:**	Encore Orthopedics, Inc.
	Submitter's address:	9800 Metric Blvd., Austin, TX 78758
	Submitter's telephone number:	(512) 834-6237
	Contact person:	Debbie De Los Santos
	Date summary prepared:	April 7, 1999
(2)	**Trade or proprietary device name:**	8mm Forged Cemented Stem
	Common or usual name:	Cemented Hip Stem
	Classification name:	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350 and Hip joint Femoral (hemi-hip) metallic cemented or uncemented prosthesis per 21 CFR 888.3360

(3) **Legally marketed predicate device:** 9mm Forged Cemented Stem (K961809)

(4) **Subject device description:**
The proximal body of the Foundation™ Non-Porous Stem is trapezoidal in cross-sectional geometry and tapers proximal to distal and lateral to medial. The proximal body has one rib on the anterior and posterior surfaces that run the length of the proximal body. Polymethylmethacrylate "buttons" are placed on the anterior, posterior, lateral and medial surfaces of the proximal body to assure that the implant is centered in the metaphseal region of the femur with a 1.5 mm cement mantle. The proximal body of the femoral stem is grit blasted to a surface of 4-6 μ. This device is fabricated from forged CoCrMo alloy.

The distal portion of the stem is conical in shape. It necks down at the distal end to receive a flanged PMMA canal centralizer. This centralizer assures that the distal stem is centered in the femoral canal and helps to maintain a even cement mantle around the distal stem. The Foundation 8mm Forged Cemented Stem has a calcar collar and has a Morse type taper to receive modular heads. The neck/stem angle is 135°.

(5) **Subject device intended use:**
The Foundation 8mm Forged Cemented Stem is intended for treatment of patients who are candidates for total or hemi-hip arthroplasty. 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 where 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. It is intended to be used with cement with acetabular components or with unipolar heads.

(6) **Basis for substantial equivalence:**
Features comparable to predicate devices include the Foundation® 9mm Forged Cemented Stems approved for commercial distribution in K961809, CoCrMo substrate, distal femoral canal centralizer, proximal cement spacers, calcar collar, proximal ribs on body, roughened proximal body, modular heads and unipolar heads.

(7) **Test Results**
This stem was analyzed using finite element analysis and is shown to survive 450 pounds for 5M cycles.

Laboratory testing of the Morse type taper was conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

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

Re: K991227
Trade Name: 8mm Forged Cemented Stem
Regulatory Class: II
Product Code: JDI
Dated: April 7, 1999
Received: April 12, 1999

Dear Ms. De Los Santos:

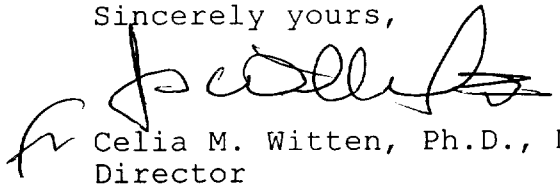
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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,



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): K991227

Device Name: _____

Indications For Use:

Foundation® 8mm Cemented Hip Stem
Indications For Use

The indications for use of the Foundation 8mm cemented 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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(per 21 CFR 801.109)
(Optional Format 1-2-96)_

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991227