JAN - 2 1998

K973809

Summary of Safety and Effectiveness

Encore Orthopedics, Inc.
9800 Metric Blvd.
Austin, TX 78758
(512) 834-6237

Trade Name: Foundation® Fracture Stem

Common Name: Press-fit hip stem

Classification Name: Hip joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3350 and Hip joint Femoral (hemi-hip) metallic uncemented prosthesis per 21 CFR 888.3360

Description: The femoral stem is straight. The proximal body is trapezoidal in cross-sectional geomety. A Morse type taper is used to receive modular heads. The neck/stem angle is 132°.

The Foundation® Fracture Stem is fabricated from wrought/forged Ti-6A1-4V. The entire stem is grit blasted. The stem is available in six sizes.

Intended Use: The Foundation® Fracture 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 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 Foundation® Fracture Stem has the same geomety, is manufactured from the same material, and has the same indications as the predicate devices.

Test Results: Testing on this device included fatigue testing and testing on the Morse type taper.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 1998

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

Re: K973809
Trade Name: Foundation Fracture Stem
Regulatory Class: II
Product Code: JDI
Dated: October 2, 1997
Received: October 6, 1997

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 requirements, 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): K97-3809

Device Name: _____

Indications For Use:

Foundation® Fracture Stem
Indications For Use

The Foundation® Fracture Stem is intended for treatment of patients who are candidates for total or hemi-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. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion and are intended to be used in a press fit mode.

(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 K97 3809