K972791

Summary of Safety and Effectiveness

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

JAN 12 1998

Trade Name: Linear™ Hip Stem

Common Name: Cemented hip stem

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

Description
When viewed in the mediolateral plane the Linear™ Hip Stem tapers slightly proximal to distal beginning at the distal border of the plasma spray. Proximal to this point the stem flares approximately 6°. The stem has a rectangular cross-sectional geometry to provide rotational stability

The Linear™ Hip Stem is fabricated from wrought/forged Ti-6Al-4V that conforms to ASTM F136. The outside surface of the stem is plasma sprayed with commercially pure titanium (ASTM F67 grade 2) to provide a roughened surface for enhanced cement fixation

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

Intended Use: The Linear 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. It is intended to be used with bone cement.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include Ti-6Al-4V substrate, straight stem, symmetric, no collar, narrow slightly taper stem in lateral view, modular heads and CP titanium plasma spray coating.

Test Results: Laboratory testing of the fatigue stem strength and Morse type taper was conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

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

Re: K972791
Trade Name: Linear™ Hip System
Regulatory Class: II
Product Code: JDI
Dated: October 28, 1997
Received: October 30, 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

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.

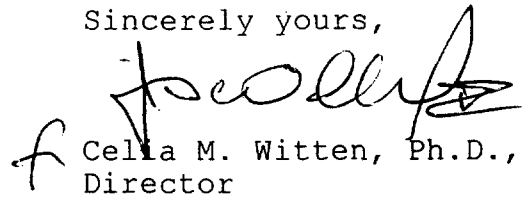
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major

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): _____

Device Name: Linear Hip Stem

Indications For Use:

Linear 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 intended to be used with cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972791

Prescription Use X (per 21 CFR 801.109) OR Over-The-Counter Use ____

(Optional Format 1-2-96)