K013490

Summary of Safety and Effectiveness

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

JAN 17 2002

Trade Name: Cemented Calcar Hip System

Common Name: Cementless hip stem

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

Description: The Cemented Calcar Hip Stem is fabricated from wrought titanium-aluminum-vanadium alloy (Ti-6Al-4V) conforming to ASTM F136. The Cemented Calcar Hip Stem is available in sizes 12-16, which have diameters from 10-14mm and lengths of 18-20cm. The proximal body is polished and designed with filleted holes for cerclage cables. The distal and lateral portions of the stem are grit-blasted. The Cemented Calcar Hip Stem is designed with a 132^{o} neck angle and a Morse taper to accept the femoral head. The distal portion of the stem tapers to accept a distal centralizer.

The Cemented Calcar Hip Stem is to be implanted either with or without a collar. The modular collar is available in a +15 and +30mm height for each size stem. The collar is attached to the stem using an attachment screw. The modular collars are fabricated from wrought titanium-aluminum-vanadium alloy (Ti-6Al-4V) conforming to ASTM F136.

The attachment screw is used to attach the collar to the Cemented Calcar hip stem. The attachment screw is fabricated from wrought titanium-aluminum-vanadium alloy (Ti-6Al-4V) conforming to ASTM F136.

Intended Use: The indications for use of the Cemented Calcar Hip System in 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. The Cemented Calcar Hip Stem is intended for use with bone cement.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Ms. Joanna Droege
Regulatory/QA Engineer
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K013490
Trade/Device Name: Cemented Calcar Hip System
Regulation Number: 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: October 18, 2001
Received: October 22, 2001

Dear Ms. Droege:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013490

510(k) Number (if known): _____

Device Name: Cemented Calcar Hip System

Indications For Use:

Cemented Calcar Hip System
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 used with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013490

OR
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