

K97 3685

DEC 19 1997

Summary of Safety and Effectiveness

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

Trade Name: Revelation™ Porous Hip Stem

Common Name: Cementless 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 Revelation™ Porous Hip Stem is fabricated from wrought/forged or cast Ti-6Al-4V that conforms to ASTM F136 or F1108, respectively. The outside surface of the stem is porous coated with commercially pure titanium (ASTM F67 grade 2) beads to provide a porous surface for enhanced fixation.

The Revelation™ Porous Hip Stem is collarless and has a Morse type taper to receive modular heads.

Intended Use: The Revelation™ Porous Hip Stem is intended for treatment of patients who are candidates for total hip arthroplasty because of 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.

Comparable Features to Predicate Device(s): The Revelation™ Porous Hip Stem has the same geometry, 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

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

DEC 19 1997

Re: K973685
Revelation Porous Hip Stem
Regulatory Class: II
Product Code: LPH
Dated: December 5, 1997
Received: December 9, 1997

Dear Ms. De Los Santos:

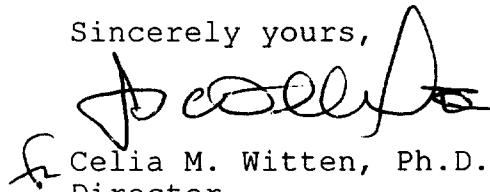
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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): K973685

Device Name: _____

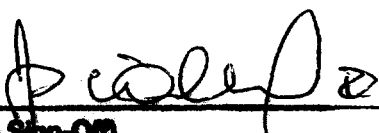
Indications For Use:

Revelation™ Porous Hip Stem
Indications For Use

The indications for use of the Revelation™ Porous 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)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973685

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_____