K993943

FEB 4 2000

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:	November 18, 1998
(2)	**Trade or proprietary device name:**	HA Coated Hip Stems
	Common or usual name:	Cementless hip stem
	Classification name:	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
(3)	**Legally marketed predicate device:**	MCS – HA Porous Coated Total Hip (Exactech) Natural-Hip Porous Stem with HA (Intermedics)

(4) **Subject device description:**
The Linear stems without HA coating were cleared for commercial distribution on K974294 and K991325; the Foundation stem on K973302 and K991226; and the Revelation on K973685. The only difference between the devices cleared in the aforementioned submissions and this is the addition of hydroxyapatite to the porous coated regions of the proximal bodies. The porous coating is plasma sprayed with hydroxyapatite (HA).

(5) **Subject device intended 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 press-fit.

(6) **Technological characteristics:**
The HA Coated Stems have the same technological characteristics (i.e., design and material) when compared to the predicate devices

(7) **Basis for substantial equivalence:**
Features comparable to predicate devices include HA coating, Ti-6Al-4V substrate, straight stem, symmetric, no collar, narrow slightly taper stem in lateral view, and modular heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2000

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

Re: K993943
Trade Name: Linear™ Porous Coated Hip Stem with HA
Foundation® Porous Coated Hip Stem with HA
Revelation™ Porous Coated Hip Stem with HA
Regulatory Class: II
Product Code: MEH
Dated: November 18, 1999
Received: November 19, 1999

Dear Ms. Los Santos:

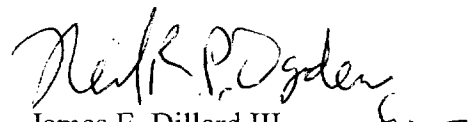
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993943

Device Name: HA Coated Hip Stems

Indications For Use:

HA Coated Hip Stems
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 press-fit.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DRD for SED

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K993943

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)