

K973614

Summary of Safety and Effectiveness

DEC 18 1997

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

Trade Name: Foundation® Unipolar Femoral Head with Modular neck length sleeve

Common Name: Unipolar head

Classification Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis per 21 CFR 888.3360.

Description: The Foundation® Unipolar head is fabricated from cast CoCrMo that conforms to ASTM F795. The modular neck length sleeve is fabricated from Ti-6Al-4V that conforms to ASTM F136.

This device is assembled by the surgeon at the time of implantation. The sleeve is placed on the taper of the femoral component and impacted into place. Next the unipolar head is placed on the taper and using the impactor is locked into place.

The unipolar head may be used with any stem that has the appropriate Morse Taper.

Intended Use: The Foundation® Unipolar femoral head is intended for treatment of patients who are candidates for hemi-hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis of 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 with any stem that has the appropriate size head. This submission includes the unipolar femoral head with a modular neck length sleeve.

Comparable Features to Predicate Device(s): The Foundation® Unipolar head 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 on the unipolar head and the modular neck length sleeve. As well as, axial pull off and torque strength of the modular neck length sleeves.



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 18 1997

Re: K973614  
Foundation® Unipolar Femoral Head  
with Modular Neck Length Sleeves  
Regulatory Class: II  
Product Code: KWL  
Dated: September 19, 1997  
Received: September 23, 1997

Dear Ms. De Los Santos:

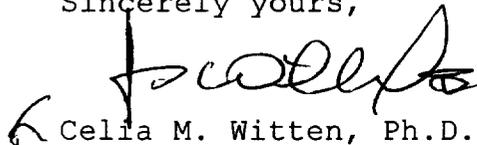
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

  
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): K973614

Device Name: \_\_\_\_\_

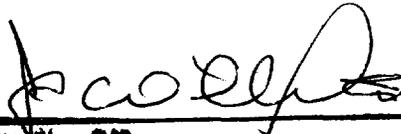
Indications For Use:

**Foundation® Unipolar Femoral Head and Modular Neck Length  
Sleeve**  
**Indications For Use**

The Foundation® Unipolar femoral head is intended for treatment of patients who are candidates for hemi-hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis of 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 with any stem that has the appropriate size head. This submission includes the unipolar femoral head with a modular neck length sleeve.

(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 K973614

Prescription Use X  
(per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)\_