

JAN 28 1998

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
9800 Metric Blvd.
Austin, TX 7875
512-832-9500

K97 4095

Trade Name: Foundation® Porous Coated Flared Rim Acetabular Cup

Common Name: Metal backed acetabular component

Classification Name: Hip joint metal/polymer semi-constrained uncemented prosthesis per 21 CFR 888.3358

Description: The Foundation® Porous Coated Flared Rim Acetabular Cup is fabricated from wrought/forged Ti-6Al-4V that conforms to ASTM F136. The outside surfaces are coated with commercially pure titanium beads (ASTM F67) for the purpose of providing a porous surface for enhanced press-fit fixation.

The flared shells are available with and without screw holes. It is hemispherical in shape and is available in sizes 44mm – 70mm.

Intended Use: The Foundation® Porous Coated Flared Rim Acetabular Cup 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. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion. The intended use is press-fit.

Comparable Features to Predicate Device(s): The spherical shape, titanium substrate, and the indexability of liners in shell and bone screw holes are features that are comparable to other devices in commercial distribution. The outside surface of the shell is porous coated to provide a porous surface for enhanced fixation.

Test Results: Testing on this device included attachment strength of liners to shell. All results are sufficient for *in-vivo* loading.



JAN 28 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K974093, K974095, and K973119
Trade Name: Foundation® Porous Coated Spiked Acetabular Cup
Foundation® Porous Coated Hemispherical Acetabular Cup
Foundation® Porous Coated Flared Rim Acetabular Cup
Regulatory Class: II
Product Code: LPH
Dated: October 28 and November 19, 1997
Received: October 30 and November 21, 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 enclosures) 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.

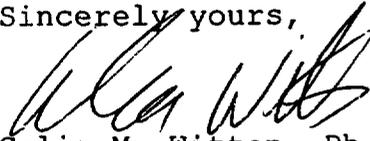
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially-equivalent 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.

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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

Enclosures

510(k) Number (if known): K974095

Device Name: FOUNDATION POROUS COATED FLARED

Indications For Use: Rim ACETABULAR CUP

Foundation® Porous Coated Flared Rim Acetabular Cup
Indications For Use

The Foundation® Porous Coated Flared Rim Acetabular Cup is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck and/or acetabulum 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. This system includes a metal-backed shell and modular polyethylene liner and is to be used press-fit. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

(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 K974095

Prescription Use +
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_