MAY - 4 2000

K993841

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 3, 1999

(2) **Trade or proprietary device name:** CEMSTOP Cement Restrictor
Common or usual name: Cement restrictor
Classification name: Class II

(3) **Legally marketed predicate device:** BIOSTOP G Cement Restrictor (Landos, Inc.)

(4) **Subject device description:**
The CEMSTOP restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurisation. Biocompatible, this device is completely resorbed within several days at 37 °C and resists the temporary temperature rise generated by polymerisation of acrylic cement.

The CEMSTOP Cement Restrictor is available in diameters of 6mm, 8mm, 10mm, 12mm, 14mm, 16mm and 20mm.

(5) **Subject device intended use:**
The CEMSTOP cement restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during total hip arthroplasty. The CEMSTOP restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurisation.

(6) **Technological characteristics:**

The CEMSTOP cement restrictor has 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 material, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2000

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

Re: K993841
Trade Name: CEMSTOP Cement Restictor
Regulatory Class: II
Product Code: LZN
Dated: March 3, 2000
Received: March 6, 2000

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 control provisions of the Act. The general control 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,

Donna R. Bachman

for 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

510(k) Number (if known): K993841

Device Name: CEMSTOP Cement Restrictor

Indications For Use:

CEMSTOP Cement Restrictor
Indications For Use

The CEMSTOP cement restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during total hip arthroplasty. The CEMSTOP restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurisation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

Donna R. Lo Cicero

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993841