510(k) Summary of Safety and Effectiveness

(1)

Submitter's name:	Encore Medical, L.P.
Submitter's address:	9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number:	(512) 834-6255
Contact person:	Joanna Droege
Date summary prepared:	March 4, 2002

(2)

Trade or proprietary device name:	Uni Knee
Common or usual name:	Knee system
Classification name:	Class II

(3) Predicate devices: Biomet Repicci II (K971938, K980665)
DePuy Preservation (K010810)
Wright Advance (K012591)

(4) Subject device description:

The Uni Knee is comprised of a femoral and a tibial component. The femoral component is manufactured from CoCr alloy conforming to ASTM F75. The femoral component is available in 4 sizes (S, M, L, XL) and provided in two configurations (left medial/right lateral and right medial/left lateral).

The Uni Knee System tibial components are manufactured from ultra high molecular weight polyethylene (UHMWPE) that conforms to ASTM F648. The tibial inserts are available in 4 sizes (29-37 mm) and 3 thicknesses (7-9 mm).

(5) Subject device intended use:

Intended for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single use implant intended for implantation with bone cement.

(6) Basis for Substantial Equivalence:

The Uni Knee is similar in design, materials and indications to the Biomet Repicci II, DePuy Preservation and Wright Advance unicondylar knee systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 4 2002

Ms. Joanna Droege
QA Engineer
Encore Medical Corporation
9800 Metric Boulevard
Austin, Texas 78758

Re: K020741
Trade/Device Name: Uni Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: March 4, 2002
Received: March 6, 2002

Dear Ms. Droege:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K020741

Device Name: Uni Knee

Indications For Use:

Uni Knee
Indications For Use

Intended for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single use implant intended for implantation with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)_

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020741

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