

AUG 23 2002

K020437
page 1 of 1

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: July 23, 2002
- (2) **Trade or proprietary device name:** Uni Knee
Common or usual name: Knee system
Classification name: Class II
- (3) **Predicate devices:** Encore Uni Knee (K020741)
Biomet Repicci II (K971938, K980665)
DePuy Preservation (K010810)
Wright Advance (K012591)

(4) **Subject device description:**

The additional components that are the subject of this **Special 510(k)** submission are the tibial inserts and baseplates. These components are to be used with the femoral components of the Uni Knee cleared in K020741.

The tibial inserts of this submission are similar to the tibial components in K020741 with the addition of a snap feature on the non-articulating side. This snap feature is meant to be used with the tibial baseplate. The tibial inserts are manufactured from UHMWPE that conforms to ASTM F648 and are available in 5 sizes (35-45 mm) and 3 thicknesses (6-8 mm).

The tibial baseplates are manufactured from CoCr alloy that conforms to ASTM F75 and are available in 5 sizes (35-45 mm) and 2 configurations (left medial/right lateral and right medial/left lateral).

(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 additional components are similar in design, materials and indications to the Encore Uni Knee cleared in K020741.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

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

Re: K022437

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: July 23, 2002

Received: July 25, 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.

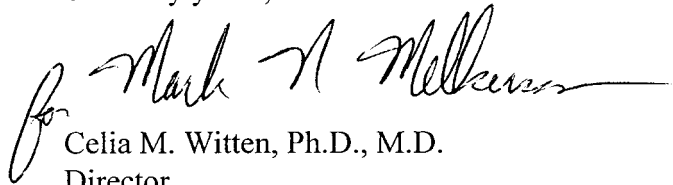
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Joanna Droege

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

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

K022437

510(k) Number (if known): K022437

Device Name: Uni Knee Additional Components

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller
Mark A. Miller
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K022437

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

SK50
OR
II