

3/17/99

K982160

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: Hinged Knee

Common Name: Hinged Knee

Classification Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis,
21 CFR 888.3510.

Description: The Hinged Knee is a tri-compartmental prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It's intended use is to allow replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The Hinged Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same indications for use, same materials and similar geometry.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

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

Re: K982160
Encore Hinged Knee
Regulatory Class: II
Product Code: KRO
Dated: February 10, 1999
Received: February 11, 1999

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial inserts available are the nominal "8mm" thick inserts, which have a minimum polyethylene thickness under the condyles of 8.0mm.
2. This device may not be labeled or promoted for non-cemented use.
3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

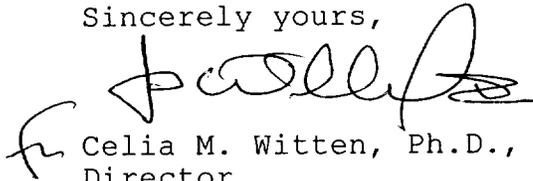
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke.

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): K982160

Device Name: Hinged Knee

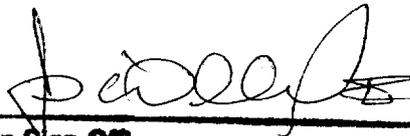
Indications For Use:

Hinged Knee
Indications For Use

The Hinged Knee is a tri-compartmental prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It's intended use is to allow replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The Hinged Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.

(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

K982160

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_