K063406

Summary of Safety and Effectiveness

JAN - 8 2007

Date: November 8, 2006

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Regulatory Affairs Specialist
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: Teffany_Hutto@encoremed.com

Trade Name: Foundation Lateral Pivot Insert

Common Name: Tibial Insert

Classification Name: Knee joint patellofemorotibial polymer/ metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description: The modification system consists of a change to the Instructions for use to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Intended Use: Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization,

K063406

Summary of Safety and Effectiveness

Date: November 8, 2006

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Regulatory Affairs Specialist
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: Teffany_Hutto@encoremed.com

Trade Name: Foundation Plasma Sprayed Femoral Component

Common Name: Femoral Knee Component

Classification Name: Knee joint patellofemorotibial polymer/ metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description: The modification system consists of a change to the Instructions for use to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Intended Use: Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization,

K063406

Summary of Safety and Effectiveness

Date: November 8, 2006

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Regulatory Affairs Specialist
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: Teffany_Hutto@encoremed.com

Trade Name: Foundation Ultra Congruent Tibial Insert

Common Name: Tibial Insert

Classification Name: Knee joint patellofemorotibial polymer/ metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description: The modification system consists of a change to the Instructions for use to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Intended Use: Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization,

K063406

Summary of Safety and Effectiveness

Date: November 8, 2006

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Regulatory Affairs Specialist
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: Teffany_Hutto@encoremed.com

Trade Name: MJS Posterior Stabilized Knee

Common Name: Total Knee System

Classification Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3530

Description: The modification system consists of a change to the Instructions for use to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Intended Use: Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Encore Medical
% Ms. Teffany Hutto
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

JAN - 8 2007

Re: K063406
Trade/Device Name: Encore Knee System IFU
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: November 8, 2006
Received: November 21, 2006

Dear Ms. Hutto:

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), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063406

Device Name: MJS Posterior Stabilized Knee

Indications for Use:

MJS Posterior Stabilized Knee
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts.

While knee replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K063406