K100900 (1/2)

JUN 18 2010

Summary of Safety and Effectiveness

Date:
June 17, 2010

Manufacturer:
Encore Medical, L.P. (d.b.a. DJO Surgical)
9800 Metric Blvd
Austin, TX 78758

Contact Person:
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Regulatory Affairs Specialist
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Product	Product Code	Regulation and Classification Name
Movation Knee System	JWH	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description:
The Movation Knee System is a tri-compartmental posterior stabilized knee for cemented applications. The system is comprised of four primary components: Femur, Tibial Insert, Tibial Baseplate, and Patella. The system is intended to treat patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. The design of the knee system is a total condylar design, increasing sagittal conformity and stability. The post and cam of the posterior stabilized design are crucial to inducing femoral rollback and providing resistance to tibial subluxation, substituting the function of the absent PCL. The tibial post in combination with the femoral cam is designed to encourage femoral roll-back on the tibia and allow clearance for deep flexion.

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;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts. This system is to be used for cemented applications

Predicate Devices:

Device Name	FOUNDATION® Knee System	3DKnee System	OPTETRAK® Total Knee System
Manufacturer	Encore Medical	Encore Medical	Exactech
510(k) Reference	K905613, K923277, K932425, K933539	K020114	K932690, K932776, K933494, K933610, K011976, K030686

Comparable Features to Predicate Device:
The Movation and Optetrak femurs exhibit an asymmetric anterior flange. The Movation knee is characterized as a total condylar knee, with kinematics guided by post and cam articulating geometry, also similar to the Optetrak Knee. The Movation femur is an anatomic component similar to the Foundation PS Knee.

The Baseplate exhibits an asymmetric perimeter, similar to the Foundation Knee, with options for a finned keel or trapezoid keel. The shape of the finned keel is similar to the Foundation knee, while the shape of the trapezoid keel is similar to the Optetrak knee.

The Posterior Stabilized Insert is a symmetric component and is similar to the Foundation PS and Optetrak PS Systems.

The Patella features a domed geometry with three pegs similar to the Optetrak Patella. The diameters are the same as Optetrak and Foundation (MTS).

The Insert and Patella are manufactured from UHMWPE, while the Baseplate and Femur are manufactured from CoCrMo. All of these materials are similar to those materials used for the Foundation, 3DKnee and Optetrak systems.

The Movation Knee System is packaged and sterilized using the same method as the 3DKnee System. Sterilization of implants is by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10-6.

Non-Clinical Testing:
Functional testing was conducted in compliance with FDA guidance, Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA, to verify that the implant performance would be substantially equivalent to predicate devices for anticipated in vivo loading via various constraint and fatigue tests.

Clinical Testing:
None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Encore Medical, L.P.
% Ms. Elizabeth Onderlinde
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

Re: K100900
Trade/Device Name: Movation Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: March 26, 2010
Received: March 31, 2010

Dear Ms. Onderlinde:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K100900

Device Name: Movation Knee System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100900