K091958 #1/2

SEP 28 2010

Summary of Safety and Effectiveness

Preparation Date: September 22, 2010

Applicant/Sponsor: Encore Medical (d.b.a. DJO Surgical)
9800 Metric Blvd
Austin, TX 78758

Contact Person: Elizabeth Pugh
Regulatory Affairs Specialist

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560), OIY, JWH, MBH

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

3DKnee	K020114	Encore Medical
E-Poly Tibial Bearings	K080528	Biomet

Device Description:
The Highly Cross-Linked Vitamin E UHMWPE (HXL VE) Tibial Inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral, compression molded and then highly cross-linked. The tibial inserts are available in 9 sizes (2- 12) and 5 thicknesses (9-19) and are provided in right and left orientations. The HXL VE Tibial Insert design is identical to the 3DKnee Tibial Insert cleared via K020114. This insert is intended to more closely match the kinematics of the knee, allowing some rotation along the medial condyle and increased congruency along the lateral condyle. The baseplate attachment mechanism is the same as the previously cleared 3DKnee System inserts.

Compatible Systems	Clearance	Cemented/Cementless
3DKnee System	K020114	Cemented
3DKnee Porous Coated Femoral Component	K032905	Cementless

Indications for Use:
Total joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;

K091956 #2/6

- 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. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

Intended Use:
DJO Surgical knee devices are intended for treatment of patients who are candidates for knee arthroplasty per the indications for use. While total 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.

Summary of Technologies:

Substantial Equivalence Table

Design Feature	Equivalent Device
Highly Cross-Linked Vitamin E Polyethylene Material UHMWPe (α-tocopherol)	E-Poly Tibial Bearings – Biomet (K080528)
Indications for Use	3DKnee Tibial Insert – Encore Medical (K020114)
Design (size, thickness, configuration, dimensions)	3DKnee Tibial Insert – Encore Medical (K020114)

Non-Clinical Testing:
The following non-clinical laboratory testing was performed to determine substantial equivalence: mechanical material characterization (Tensile, Small Punch, Izod Impact, and crack propagation), physical and chemical characterization (Oxidation Index, Compressive Modulus, Poisson's Ratio, Surface Roughness, Density, Onset Melting Temperature, Peak Melting Temperature, Delta H, Degree of Crystallinity, Crosslink Density, Swell Ratio, Molecular Weight, Polydispersity Index, Lamallae Thickness, Free Radical Concentration, Vitamin E Concentration, Vitamin E Consolidation, Vitamin E Elution/Extraction, Trans-vinylene Index), tibial insert peel-out strength, wear testing, and biocompatibility. All testing has demonstrated the device is substantially equivalent to the predicate devices.

Clinical Testing:
None provided as a basis for substantial equivalence.

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

Encore Medical, L.P.
% Mrs. Beth Pugh
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

SEP 28 2010

Re: K091956
Trade/Device Name: Highly Cross-linked Vitamin E UHMWPE Tibial Inserts
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/ polymer semi-constrained cemented prothesis
Regulatory Class: Class II
Product Code: OIY, JWH, MBH
Dated: July 29, 2010
Received: July 30, 2010

Dear Mrs. Pugh:

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

SEP 2 8 2010

510(k) Number (if known): K091956

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert

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. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

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

510(k) Number K091956