510(k) Summary

JUN 2 1 2013

Date: June 20, 2013

Manufacturer:
Encore Medical, L.P.
Trade Name: DJO Surgical
9800 Metric Blvd
Austin, TX 78758

Contact Person:
William Garzon
Regulatory Affairs Specialist
Phone: (512) 834-6391
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Email: william.garzon@djoglobal.com

Product	Classification	Product Code
TaperFill™ Femoral Hip Stem	Class II	LPH and LZO

Product Code	Regulation and Classification Name
LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310

Description:
The purpose of this application is to include a new line extension to the current Linear™ Porous Coated Hip Stem. The TaperFill Femoral Hip stem is designed with a reduced neck, shorter length, and increased proximal width as compared to the predicate Linear™ Hip Stem (K974294).The TaperFill™ stem has an equivalent or larger cross section area in all locations.

The TaperFill™ Femoral Hip Stem is fabricated from wrought/forged Ti-6A1-4V that conforms to ASTM F136. The outside surface of the stem is porous coated with commercially pure titanium (ASTM F67 grade 2) to provide a porous surface.

There are no changes to materials, sterilization, packaging, or method of manufacture. The major dimensional changes are isolated below the calcar line, with TaperFill incorporating a larger anterior-posterior cross-sectional width and a reduced overall stem length. The critically stressed neck regions of the stem and the modular taper that mates with the existing modular heads are identical to the cleared Linear™ Hip Stem (K974294).

Indications for Use:
Joint replacement is indicated for patients suffering from disability due to:
- Noninflammatory degenerative joint disease
including osteoarthritis and avascular necrosis of the natural femoral head
- Rheumatoid arthritis
- Correction of functional deformity
- Femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.
The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or

intra-operative instability and for who all other options to constrained acetabular components have been considered.
This stem is to be press-fit. This stem is intended for cementless use.

Predicate Device:

- Linear™ Porous Coated Hip Stem – K974294
- P² Coating on Linear Stem– K081679
- P² Coating on Linear Hip Stem Size 8 – K120241

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

Non-Clinical Testing: Dimensional analysis, range of motion analysis

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 21, 2013

Encore Medical, L.P.
% Mr. William Garzon
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

Re: K130099
Trade/Device Name: TaperFill™ Femoral Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWZ
Dated: April 17, 2013
Received: April 23, 2013

Dear Mr. Garzon:

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 contact 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. 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,

Anton E. Dmitriev

For Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130099

Device Name: Taperfill™ Femoral Hip Stem

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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)

Elizabeth L. Frank -S

Division of Orthopedic Devices