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510(k) Summary K140902 (pg 1/2)

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the E1® Series A® Patella 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Amy L Walriven
Senior Regulatory Affairs Specialist

Date:
April 3, 2014

Subject Device:
Trade Name: E1® Series A® Patella
Common Name: Total Knee Replacement - Patella Component

Classification Name:
- JWH – Prosthesis, Knee, Patellofemoraltibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- MBH – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- MBV – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, UHMWPE, Pegged, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- OIY – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (21 CFR 888.3560)

Legally marketed devices to which substantial equivalence is claimed:
- Vanguard Asymmetrical Patellar Component (K110362)
- Vanguard Patella Components (K040770)
- E-Poly (aka E1) Tibial Bearings (K080528) – reference for material and manufacturing process

Device Description
The E1® Series A® Patellae is an all-polyethylene, 3-peg patella series intended for replacement of part of the knee joint in conjunction with a femoral and tibial component in primary or revision applications. Patella components are available in standard and asymmetric configurations. The proposed devices are manufactured from UHMWPE per ASTM F648 exposed to 100 kGy gamma irradiation and Vitamin E (α-tocopherol).

The E1® Series A® Patellae are compatible with Biomet cruciate retaining (CR), posterior stabilized (PS), and constrained (SSK) knee replacement systems.

Intended Use and Indications for Use

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Tibial bearings are indicated for use with both cemented and uncemented Biomet tibial trays.
All-polyethylene patellar components are indicated for cemented use only.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed E1® Series A® Patellae and predicate patella devices have the same intended use.
- **Indications for Use:** The proposed E1® Series A® Patellae and predicate patella devices have the same indications for use.
- **Materials:** The proposed E1® Series A® Patellae and predicate patella devices are manufactured from UHMWPE per ASTM F648. The proposed devices utilize the same material and manufacturing process the Biomet E1 Tibial Bearings, K080528.
- **Design Features:** The proposed E1® Series A® Patellae incorporate the same design features as the predicate patella devices.
- **Sterilization:** The proposed E1® Series A® Patellae and predicate devices are provided sterile via the same sterilization methods for single-use.

Summary of Performance Data

Results from mechanical tests and engineering analyses demonstrate the proposed E1® Series A® Patellae are substantially equivalent to the predicate patella devices. No animal or clinical testing was required to support substantial equivalence. A description of the tests and analyses is listed below.

- Contact area stress analysis and engineering analysis
- Mechanical stability analysis and engineer analysis
- Peg shear testing

Substantial Equivalence Conclusion

The proposed E1® Series A® Patellae have the same intended use and indications for use as the predicate patella devices. Performance test data and analyses demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.

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

July 3, 2014

Biomet, Incorporated
Ms. Amy Walriven
Senior Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K140902
Trade/Device Name: E1® Series A® Patellae
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, MBV, OIY
Dated: April 2, 2014
Received: April 9, 2014

Dear Ms. Walriven:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140902 (pg 1/1)

Device Name: **E1® Series A® Patellae**

INDICATIONS FOR USE:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Tibial bearings are indicated for use with both cemented and uncemented Biomet tibial trays.
All-polyethylene patellar components are indicated for cemented use only.

Prescription Use ☒ *(Part 21 CFR 801 Subpart D)* AND/OR **Over-The-Counter Use** ☐ *(21 CFR 801 Subpart C)*

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices