



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biomet Inc.
Ms. Heidi Busz
Regulatory Affairs Associate
56 East Bell Drive
Warsaw, Indiana 46581

August 30, 2017

Re: K171540
Trade/Device Name: Refobacin Bone Cement R
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: July 17, 2017
Received: July 18, 2017

Dear Ms. Busz:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Katherine D. Kavlock -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K171540

Device Name
Refobacin Bone Cement R

Indications for Use (Describe)

Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Refobacin® Bone Cement R 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.
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Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact Person: Heidi Busz
Regulatory Affairs Associate
Telephone: (574-372-4249)
Fax: fax (574-372-4710)

Date: May 23, 2017

Subject Device: **Trade Name: Refobacin Bone Cement R**
Common Name: Bone Cement

Classification Name:

- LOD, MBB – Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)

Predicate Device(s):

K031673	PALACOS® G Bone Cement	Heraeus Kulzer GmbH & Co.
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The product obtained for testing and labeling comparison is labeled as PALACOS® R+G.

Device Description: **Refobacin® Bone Cement R** is a fast setting acrylic cement containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X-ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation.

Indications for Use: **Refobacin Bone Cement R** is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and

other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Summary of Technological Characteristics:

The intended use, indications for use, materials, sterilization methods, cement design, and principle of operation of the subject device are the same as the predicate device. Differences in size offerings and shelf life do not introduce any new risks of safety and efficacy. Refobacin® Bone Cement R is substantially equivalent to PALACOS® G for the primary intended use of fixation of prosthetic components as described in the device labeling.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
 - Comparative in-vitro testing was performed and the results for Refobacin® Bone Cement R were compared to that of the predicate, PALACOS® G. The results showed that Refobacin® Bone Cement R possesses mechanical, chemical, physical and handling characteristics necessary to fulfill the intended use. Refobacin® Bone Cement R is substantially equivalent to PALACOS® G for the primary intended use of fixation of prosthetic components as described in the device labeling.
 - Bacterial Endotoxin Testing (BET)
 - BET demonstrated the pyrogen limit specifications have been met.
- **Clinical Tests:**
 - Clinical data was not required to establish substantial equivalence between the subject Refobacin® Bone Cement R and the predicate device.

Substantial Equivalence Conclusion

Based on the similarities in design, function, indications for use and fundamental scientific technology, the subject device is similar to the predicate device and does not introduce any new risks of safety or efficacy. Therefore, Biomet concludes that the subject device is substantially equivalent to the predicate device.