Synthes (USA) Products, LLC
Christopher J. Medberry, Ph.D.
Project Leader, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K170802
Trade/Device Name: TRAUMACEM™ V+ Injectable Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD
Dated: August 25, 2017
Received: August 25, 2017

September 28, 2017

Dear Dr. Medberry:

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,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

The TRAUMACEM™ V+ Injectable Bone Cement is indicated for augmentation of the TFN-ADVANCED® Proximal Femoral Nailing System through cannulated implants and instruments for patients with poor bone quality (e.g., osteoporosis).

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

- [x] 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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<th><strong>Sponsor:</strong></th>
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| **Date Prepared:** | September 28th, 2017 |
| **Proprietary Name:** | TRAUMACEM™ V+ Injectable Bone Cement |
| **Classification:** | Classification: 888.3027  
Product Code: LOD |
| **Predicate Device:** | Simplex P (K062553) - primary |
| **Reference Devices:** | BonOs Inject (K090460), Vertecem (K090435), Vertecem II (K121876) |
| **Device Description:** | TRAUMACEM™ V+ Injectable Bone Cement consists of sterile packed powder and liquid components to create radiopaque TRAUMACEM™ V+ Injectable Bone Cement. The powder component is pre-packed in the mixer. The liquid component is stored in a glass ampoule. A transfer lid for the mixing and transfer of the bone cement in the application system is also contained in the kit. Mixing the two sterile components produces the injectable bone cement. |
| **Indications for Use:** | The TRAUMACEM™ V+ Injectable Bone Cement is indicated for augmentation of the TFN-ADVANCED® Proximal Femoral Nailing System through cannulated implants and instruments for patients with poor bone quality (e.g., osteoporosis). |
| **Substantial Equivalence:** | The proposed TRAUMACEM™ V+ Injectable Bone Cement has comparable indications, design characteristics, materials, and performance characteristics in comparison to the predicate device. |
Summary Comparison of Technological Characteristics

In specific, the subject, predicate, and reference devices are self-polymerizing two-component systems comprising a powder and a liquid that polymerize at room temperature immediately after they are mixed together in an exothermic reaction. The major powder component of the subject and predicate devices is acrylic polymer. The indications for the TRAUMACEM™ V+ Injectable Bone Cement are highly similar to a subset of the indications for predicate device Simplex P (K062553) and utilized in the same patient population (e.g., patients with poor bone quality or loss of bone substance). Both TRAUMACEM™ V+ Injectable Bone Cement and Simplex P (K062553) meet the requirements of ASTM F451-08/ISO 5833:2002 (apart from setting and dough time). The major differences between the subject and predicate cement are radiopacity and handling properties. TRAUMACEM™ V+ Injectable Bone Cement was designed to have increased radiopacity and working time to facilitate delivery through cannulated implants and instruments. As these differences influence physical and chemical properties, the subject device was then compared to reference devices BonOs Inject (K090460) and Vertecem (K090435) to demonstrate compliance with the Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA (dated July 17th, 2002). Reference device Vertecem II (K121876) was also included as a material reference in support of the biological risk evaluation.

The following performance tests have also been provided in support of this 510(k):

- Biomechanical evaluation of cut-out resistance
- Cadaveric evaluation of cut-out resistance
- Cannulated implant removal evaluation
- Radiopacity comparison
- Cytotoxicity
- Irritation
- Sensitization
- Material mediated pyrogenicity
- Genotoxicity (*in vitro and in vivo*)
- Implantation
- Chemical characterization.

Summary of Clinical Evidence

Three clinical studies conducted outside the US were presented in support of the subject device. One was a prospective, multicenter, randomized, postmarket study comparing outcomes in patients with unstable trochanteric fractures that were treated with or without Traumacem V+ Injectable Bone Cement Augmentation. Two were
summaries of peer-reviewed publications summarizing the short-term and long-term outcomes of patients with trochanteric fractures who were treated with cephalomedullary nail augmentation with PMMA bone cements. The three studies were evaluated with respect to clinical indications, method of use and patient populations, which were confirmed to align with the intended use of the subject device. No cases of cut-out were observed. Potential risks associated with augmentation (e.g., cement leakage) had a low rate of occurrence. These data correlated well with presented real-world market experience on the use of Traumacem V+ Injectable Bone Cement outside the United States.

**Conclusions**

Overall, the performance testing and clinical evidence from the postmarket randomized study, postmarket case series, and outside the US market experience support that the benefits of using Traumacem V+ Injectable Bone Cement outweigh the potential risks when utilized in accordance with its indications for use and supports the substantial equivalence of the subject device.