June 10, 2019

Zimmer Knee Creations
% Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K190814
Trade/Device Name: AccuFill Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, FMF
Dated: March 29, 2019
Received: March 29, 2019

Dear Ms. Rhodes:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K190814

Device Name
AccuFill Bone Substitute Material

Indications for Use *(Describe)*

AccuFill Bone Substitute Material is an injectable, self-setting, macroporous, osteoconductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e., posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. AccuFill BSM is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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

Manufacturer: ETEX Corporation
55 Messina Drive
Braintree, MA 02184

Contact: Mr. David L. Nichols
Vice President, General Manager
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Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: May 31, 2019

Device Trade Name: AccuFill Bone Substitute Material

Common Names: Bone void filler
Piston Syringe

Regulations: 21 CFR 888.3045 – Resorbable calcium salt bone void filler device
21 CFR 880.5680 – Piston syringe

Classification: Class II

Product Codes: MQV, FMF

Indications for Use:
AccuFill Bone Substitute Material is an injectable, self-setting, macroporous, osteoconductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e., posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. AccuFill BSM is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Device Description:
AccuFill Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of hydration fluid and mixed. Once mixed, the resulting paste is used to fill osseous defects. The paste can be administered to the treatment site by injection or by manual application. AccuFill hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly

crystalline hydroxyapatite ("PCHA"), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone minerals. AccuFill is an osteoconductive material that is resorbed and replaced by natural bone over time.

AccuFill BSM is available in two packaging configurations: (1) AccuFill BSM is sold in a jar and can be mixed in a bowl or mixing syringe; (2) AccuFill BSM is also sold in a prefilled mixing syringe. AccuFill BSM is delivered to the osseous defect site with stainless steel AccuPort cannulas.

Predicate and Reference Devices:
OssiPro (ETEX Corp., K062630), CarriGen® Porous Bone Substitute Material (ETEX Corp., K093447 and K101557), and CarriGen PF (ETEX Corp., K182107) serve as predicates. The BioCUE bone marrow aspiration needle (BK100027) serves as a reference device.

Performance Testing:
All necessary testing has been performed to assure the substantial equivalence of AccuFill to the predicate devices, and demonstrate the device performs as intended.

The following performance testing was performed:

- Simulated Use/Extrusion Testing
- Working Time
- Setting Time
- Compression Strength
- Biocompatibility Evaluation
- Bacterial Endotoxin Test (BET) to establish that the device meets pyrogen limit specifications
- Sterility Validation Testing
- Shelf-Life and Packaging Validation Testing

Substantial Equivalence:
AccuFill Bone Substitute Material is substantially equivalent to the predicate devices based on indications for use, technological characteristics, design, material, mechanical performance testing, method of application, packaging and sterilization. Predicate devices K062630, K093447 and K101557 are synthetic calcium phosphate bone graft substitutes; the subject device's chemical composition and manufacturing processes are identical to those of the predicate bone substitute material. When AccuFill is prefilled in a mixing syringe, it is identical to CarriGen PF cleared in K182107. Subchondroplasty (i.e., the filling of subchondral osseous defects with AccuFill) is within the scope of the cleared indications for use of the identified predicates (i.e., CarriGen, K093447 and K101557; and CarriGen PF, K182107). AccuFill is identical to these predicates with respect to its indications for use in (e.g., filling osseous defects in the extremities) and is subject to the stipulations included within the warnings and precautions in the device's labeling. The AccuPort cannulas are substantially equivalent to the needles used for delivery of CarriGen to an osseous defect.