August 31, 2018

ETEX Corporation
% Stacy Hutchens
Scientific Affairs Manager
Zimmer Biomet
1800 West Center Street, MS 1901
Warsaw, Indiana 46580

Re: K182107
Trade/Device Name: CarriGen® PF
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, FMF
Dated: August 3, 2018
Received: August 3, 2018

Dear Ms. Hutchens:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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)*
K182107

Device Name
CarriGen® PF

Indications for Use *(Describe)*
CarriGen Porous Bone Substitute Material is an injectable, self setting, macro-porous, osteo-conductive, 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. CarriGen 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
38 Sidney Street
Cambridge, MA 02139

Contact: Ms. Stacy Hutchens
Scientific Affairs Manager
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Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: August 3, 2018

Device Trade Name: CarriGen® PF

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:
CarriGen Porous Bone Substitute Material is an injectable, self setting, macro-porous, osteo-conductive, 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. CarriGen is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Device Description:
CarriGen Porous Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. CarriGen PF is a mixing syringe pre-filled with the previously cleared CarriGen Porous

Bone Substitute Material. The CarriGen PF system eliminates the need to transfer the CarriGen powder to the mixing syringe. After mixing, CarriGen is administered to the treatment site by manual application. The material can be shaped into a desired form *in situ* prior to implantation. After the putty is applied to the treatment site, it 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. CarriGen Porous Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Predicate Devices:
OssiPro (ETEX Corp., K062630) and CarriGen® Porous Bone Substitute Material (ETEX Corp., K093447 and K101557) serve as predicate devices with the ETEX Mixing and Delivery System (ETEX Corp., K141245) serving as a reference predicate device.

Performance Testing:
All necessary testing has been performed to assure the substantial equivalence of CarriGen PF 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

Substantial Equivalence:
The modified CarriGen PF is substantially equivalent to the predicate devices based on indications for use, technological characteristics, design, material, mechanical performance testing, packaging and sterilization. Predicate devices K062630, K093447 and K101557 are synthetic calcium phosphate bone graft substitutes; the subject device chemical composition and manufacturing processes are identical to those of the predicate devices. The mixing syringe component and method of application of the subject device are substantially equivalent to that of the reference predicate (K141245). The information summarized in the Design Control Activities Summary demonstrates that the CarriGen PF meets the pre-determined acceptance criteria for the verification activities.