Elute, Inc.
Ashok Khandkar, PhD
CEO
417 Wakara Way Suite 3510
Salt Lake City, Utah 84108

August 6, 2018

Re: K180853
Trade/Device Name: EP Granules™ BVF
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: June 29, 2018
Received: July 5, 2018

Dear Dr. Khandkar:

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.

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,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180853

Device Name

EP Granules™ BVF

Indications for Use *(Describe)*

EP Granules™ BVF is an implant intended to fill bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. EP Granules™ BVF resorbs and is replaced with 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.

K180853 510(k) Summary

Submitter: Elute, Inc.

Contact Person: AK Khandkar, PhD - CEO
417 Wakara Way. Suite 3510
Salt Lake City, UT 84108
801-696-4716

Date Prepared: March 29, 2018

Trade Name: EP Granules™ BVF

Classification Name: Resorbable calcium salt bone void filler device
21 CFR §888.3045, Product Code MQV, Class II

Predicate Device(s): K990131, ProOsteon 500R bone graft substitute (1º predicate); K082073, Actifuse Flow bone graft substitute (additional predicate)

Device Description:

EP Granules™ BVF is an osteoconductive device comprising hydroxyapatite (HA) and calcium carbonate ($CaCO_3$) and calcium chloride ($CaCl_2$) particles bound together with a degradable polymer-based binding matrix of poly(caprolactone) (PCL), poly(ethylene glycol) (PEG), and poly(lactide-co-glycolide) (PLGA). The hydroxyapatite and calcium carbonate particles are dispersed throughout the entire structure of the device. Upon implantation, the ceramic hydroxyapatite and calcium carbonate particles resorb over time. The polymer-based binding matrix also resorbs over time. It is supplied sterile in a granulated form of various sizes. When *EP Granules™ BVF* is placed in direct contact with viable non-infected bone, porous regions form in the device and are infiltrated with bone tissue. Bone formation occurs in apposition to the hydroxyapatite and calcium carbonate surface and within the pores of the device. As the device resorbs, bone and soft tissue grow into the space previously occupied by the device.

Indications For Use:

EP Granules™ BVF is an implant intended to fill bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. EP Granules™ BVF resorbs and is replaced with bone during the healing process.

Comparative Analysis:

It has been demonstrated that the *EP Granules™ BVF* device is comparable to the predicate devices in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The *EP Granules™ BVF* device has been fully assessed within Elute's Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm safety and effectiveness.

Technology Comparison of EP Granules™ BVF with Predicate Device:			
	Subject Device –	**1° Predicate (K990131)**	**Additional Predicate (K082073)**
Device Name	**EP Granules™ BVF**	**Pro Osteon 500 R Bone Graft Substitute**	**Actifuse Flow Bone Graft Substitute**
Intended Use	Bone Graft Substitute	Bone Graft Substitute	Bone Graft Substitute
Indications for use	EP Granules™ BVF is an implant intended to fill bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. EP Granules™ BVF resorbs and is replaced with bone during the healing process.	Pro Osteon 500 R Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Pro Osteon 500 R is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.	Actifuse Flow is intended only for orthopaedic applications as filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse Flow Bone Graft Substitute can be injected into bony voids or gaps of the skeletal system, i.e., extremities and pelvis with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced by bone during the healing process.
Prescription (Rx Only)	Yes	Yes	Yes
Classification	Orthopedic Devices-Resorbable Calcium Salt Bone Void Filler 21 CFR §888.3045, Product code: MQV Class II	Orthopedic Devices-Resorbable Calcium Salt Bone Void Filler 21 CFR §888.3045, Product code: MQV Class II	Orthopedic Devices-Resorbable Calcium Salt Bone Void Filler 21 CFR §888.3045, Product code: MQV Class II

Anatomical site	Within voids or gaps that are not intrinsic to the stability of the bony structure.	Within voids or gaps that are not intrinsic to the stability of the bony structure.	Within voids or gaps that are not intrinsic to the stability of the bony structure.
Where Used	Operating Room or Surgical Suite	Operating Room or Surgical Suite	Operating Room or Surgical Suite
Morphology	Granules and croutons of calcium salts with resorbable polymer binder	Particles, granules & blocks of calcium salts	Hydrated putty of calcium salt granules with resorbable polymer binder
Fundamental Scientific Technology	Once implantation, the ceramic hydroxyapatite and calcium carbonate particles slowly resorb over time, allowing for new bone growth.	Once implanted, the calcium phosphate outer layer will slowly resorb, delaying exposure of the underlying and faster resorbing calcium carbonate	Once implanted resorbable polymers bind and deliver osteo-conductive calcium salt particles to be used as a bone void filler
Sterilization	Gamma irradiation	Gamma irradiation	Provided Sterile, Method Unknown
Bioactivity	Osteo-conductive	Osteo-conductive	Osteo-conductive & Osteo-stimulatory

Functional/Safety Testing:

The following functional tests were performed. All data met pre-determined acceptance criteria.

- **Bench-top Testing:**
  - *In-Vitro* degradation and surface characterizations of *EP Granules™ BVF* formulation
  - X-ray diffraction (XRD) and compressive mechanical testing of *EP Granules™ BVF* formulation from an Accelerated Shelf-Life Study
  - *In-vitro* pH exposure study of *EP Granules™ BVF*

- **Pre-Clinical Testing** –Large animal models, i.e. as critical size defect model, under an IACUC approved protocol

- **Biocompatibility** – Per ISO 10993-1 for Implant Devices, Tissue/bone Contact, Permanent contact (> 30 days) including:
  - Cytotoxicity
  - Sensitization
  - Irritation/ Intracutaneous Toxicity
  - Systemic Toxicity (Material Mediated pyrogenicity)
  - Sub-Acute Toxicity
  - Genotoxicity
  - Implant Study
  - Bacterial Endotoxin (LAL -Pyrogenicity)

Conclusion:

The *EP Granules BVF* device is substantially equivalent to the cited predicate devices. Additionally, the *EP Granules BVF* device met all acceptance criteria to confirm safety and effectiveness.