February 26, 2025

Elute Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K250346
Trade/Device Name: BonVie+
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: February 6, 2025
Received: February 6, 2025

Dear Janice Hogan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.02.26 09:16:46 -05'00'

Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250346

Device Name

BonVie+

Indications for Use *(Describe)*

BonVie+ 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. BonVie+ 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250346

510(K) SUMMARY

Elute, Inc.'s BonVie+

Submitter:

Elute, Inc.
417 Wakara Way, Suite 3510
Salt Lake City, UT
84108

Contact Person: Dr. Ashok Khandkar, CEO

Phone: (801) 696-4716

Email: ak@elutinc.com

Correspondent:

Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia PA
19103

Contact Person: Janice M. Hogan

Phone: (267) 675-4611

Email: janice.hogan@hoganlovells.com

Date Prepared: February 6, 2025

Name of Device:

BonVie+

Common or Usual Name: Resorbable calcium salt bone void filler device

Classification Name: Filler, Bone Void, Calcium Compound

Regulation Number: 888.3045

Product Code: MQV

Predicate Information:

Predicate Device: EP Granules™ BVF

Predicate Applicant: Elute, Inc.

Predicate 510(k) Number: K180853

Predicate Manufacturer: Elute, Inc.
417 Wakara Way, Suite 3510
Salt Lake City, UT
84108

Predicate Produce Code: MQV

Device Description:

BonVie+ is an osteo-conductive bone void filler. It is supplied sterile in a kit comprised of 1] a pack containing polymers and Ca-salt in powdered form, 2] ampoules containing a biocompatible solution (acetone) for mixing and granulation, and 3] a silicone mat containing cavities of various sizes to form granules of various sizes. The powder formulation comprises hydroxyapatite (HA), calcium carbonate ($CaCO_3$), and calcium chloride ($CaCl_2$) particles with degradable polymers poly(caprolactone) (PCL), poly(ethylene glycol) (PEG), and poly(lactide-co-glycolide) (PLGA). The biocompatible solution used for mixing is acetone. Once mixed and granulated, the HA and $CaCO_3$ particles are dispersed throughout the entire structure of the device. Upon implantation, the HA and $CaCO_3$ particles resorb over time. The polymer-based binding matrix also resorbs with time. When BonVie+ is placed in direct contact with viable bone and the surrounding biologic fluid environment, porous regions form in the filler material and are infiltrated with bone tissue. Bone formation occurs in apposition to the HA and $CaCO_3$ surface and within the pores of the device. As the device resorbs, bone grows into the space previously occupied by the filler material.

Intended Use / Indications for Use:

BonVie+ 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. BonVie+ resorbs and is replaced with bone during the healing process.

Indications for Use Comparison:

The indications for use are the same as the predicate device.

Technological Comparison:

The subject and predicate device have the same chemical composition. They differ in how they are manufactured. While the predicate was provided in preformed granules, the subject device is provided as a powder and solution that can be used, in addition with the provided silicone mat, to fabricate bone

void filler granules of the desired shape and size. As the available shapes and sizes are equivalent to the predicate device, this does not raise different types of questions.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

- In-vitro Degradation and Surface Characterizations of BonVie+
- X-ray Diffraction (XRD) of BonVie+
- Residual Solution in BonVie+ granules
- Usability Testing
- Compression testing
- Sterilization and packaging validation
- Biocompatibility testing in accordance with ISO 10993
- Pyrogenicity testing/endotoxin monitoring.

Conclusion

BonVie+ is substantially equivalent to its predicate device.