November 6, 2024

Acuitive Technologies, Inc.
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7W3J6
Canada

Re: K240450
Trade/Device Name: Citrepore™
Regulation Number: 21 CFR 888.3045
Regulation Name:
Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: October 7, 2024
Received: October 7, 2024

Dear Robert Poggie:

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,

Robert M. Stefani -S
2024.11.06 11:59:57 -05'00'

For: 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)*

K240450

Device Name

Citrepore™

Indications for Use *(Describe)*

CITREPORE™ is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. CITREPORE is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. CITREPORE is intended to be used for filling bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, CITREPORE 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.

Traditional 510(K) Notification for Citrepore™

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information summarizes the safety and effectiveness of Acuitive Technologies' CITREPORE™.

SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint Louis, Notre-Dame-de-L'Ile-Perrot, QC J7W 3J6, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	514-901-0796
Date of Submission:	November 6, 2024

DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Acuitive Technologies, Inc.
Manufacturer Address:	50 Commerce Drive, Allendale, NJ 07401, USA
Registration Number:	10079115
Contact Name:	Matthew Poggie
Title:	Senior VP of RA / QA
Device Trade Name:	CITREPORE™
Classification Code:	MQV
Classification Panel:	Orthopedic
Regulation Number and Name:	21 C.F.R. § 888.3045 Resorbable Calcium Salt Bone Void Filler Device

PRIMARY PREDICATE DEVICE

K083033	Vitoss BA2X Bioactive Bone Graft Substitute

REFERENCE DEVICES

K200725	Citregen Tendon Interference Screw (TIS) and Citrelock
K210239	Citrespline and Citrelock ACL Implants
K221468	Acuitive Technologies Citregen Bone Anchor Devices
K232592	Citrelock DUO

INDICATIONS FOR USE

CITREPORE™ is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. CITREPORE is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. CITREPORE is intended to be used for filling bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, CITREPORE resorbs and is replaced with bone during the healing process.

Device Description

CITREPORE™ is a synthetic, highly porous, resorbable bone void filler fabricated from a polymer bioceramic composite comprised of 60 wt.-% polymer and 40 wt.-% ASTM F1538 45S5 Bioactive Glass. The polymer component is a citrate-based network of completely amorphous polymer chains crosslinked together to form an elastomeric material. Bioactive Glass is a biologically compatible synthetic material consisting of silicates, sodium, calcium oxides, and phosphates. The constituent materials (citrate, Ca, P, O, H, Si) exist naturally in normal bone.

CITREPORE is provided to the end user in a variety of shapes and sizes that facilitates new bone formation across the graft site and throughout the interconnected porous structure. CITREPORE is pliable and sponge-like and can be cut to fit the bony defect using traditional instruments that are available in the OR at the time of surgery. At the time of surgery, CITREPORE can be infused with autologous blood, bone marrow aspirate, and/or other fluids. As body fluids penetrate the device, surface erosion of the polymer phase occurs through hydrolysis of the ester bonds located between the monomers and at the crosslink sites. Upon implantation, the Bioactive Glass component of CITREPORE undergoes a surface modification that provides for direct bonding to surrounding bone via an apatite layer (i.e., bioactive). CITREPORE is single use and provided sterile.

MATERIALS: POC (poly-octamethylene-citrate) and ASTM F1538 45S5 Bioactive Glass.

COMPARSION OF TECHNOLOGICAL CHARACTERISTICS

The subject CITREPORE and predicate Vitoss BA2X devices are bone void fillers regulated by the FDA per CFR 21 888.3045, product code MQV, with the same indications for use except that the predicate includes use in the spine. The following points compare the subject and predicate device characteristics.

- Citrepore is > 80% porous with average pore size of 373 microns. The predicate device is highly porous with similar range of pore sizes.
- Citrepore is offered in an array of pre-formed shapes (strips, squares, wedges, ovals, spheres, cylinders) ranging in volume from 0.1cc to 12.5cc. Vitoss is offered in an array of pre-formed shapes (block, pack, strip) ranging in volume from 1.2cc to 10cc. Vitoss is also offered as morsels, Citrepore is not.
- Citrepore can be cut and morselized by pulling apart by hand or cutting with instruments available in the operating room (OR), as can the predicate device.

- Citrepore is hydrophilic, as is the predicate device.
- Citrepore was determined to be biocompatible per ISO 10993-1 testing, as was the predicate.
- Citrepore was shown to be osteoconductive in an in vivo rabbit defect model with 3-days, 4, 8, 13, and 26-weeks follow-ups that compared Citrepore to the predicate Vitoss BA2X wherein bone healing was confirmed with radiographic, histopathological, and histomorphometric analyses.
- Citrepore was shown to be bioactive in an in vitro study that confirmed growth of surface apatite.
- The subject and predicate devices are single use and provided sterile (gamma radiation).

A comparison of technological characteristics of the subject Citrepore and predicate Vitoss devices demonstrate substantial equivalence.

PERFORMANCE DATA

Performance tests, V&V, and notable results for Citrepore are listed below.

- Citrepore is > 80% porous with average pore size of 373 microns, as determined by mercury intrusion porosimetry and SEM measurements.
- As evidenced by passive wicking of PBS (5 minutes soak time), Citrepore's mass increased by 4.0 X for whole implants and 7.2 X for morsels. Handling and use was verified via bench tests.
- Biocompatibility testing per ISO 10993-1 (2018) and toxicological risk assessment established the biocompatibility and safety of Citrepore.
- Citrepore was shown to be bioactive in an in vitro study that confirmed growth of a surface apatite-layer when the device was submerged in simulated body fluid containing the same ion concentrations as human blood plasma.
- Validation of gamma sterilization was performed per ANSI/AAMI/ISO TIR 13004:2013/(R) 2016 (VDmax20).
- Osteoconductivity was demonstrated via functional animal modeling (i.e., rabbit, critical defect).
- Stability of packaging and the Citrepore device was verified and validated for the labelled shelf life.

CONCLUSIONS

Based on the indications for use, technological characteristics, pre-clinical bench testing, functional animal model, and V&V activities summarized herein, Acuitive Technologies, Inc. has determined that the subject device CITREPORE™ is substantially equivalent to the cited legally marketed predicate device.