September 20, 2023

Acuitive Technologies, Inc.
% Robert Poggie, PhD
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7W 3J6
Canada

Re: K232592
Trade/Device Name: CITRELOCK® DUO
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: August 24, 2023
Received: August 25, 2023

Dear Robert Poggie, PhD:

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2023.09.20 15:47:35 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232592

Device Name

CITRELOCK® DUO

Indications for Use *(Describe)*

The CITRELOCK® DUO is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. More specifically:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendon Reattachment, Acromion-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist.

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.

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510(k) Summary

Special 510(K) Device Modification
CITRELOCK® DUO

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

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint Louis, Notre-Dame-de-L'lle-Perrot, QC J7W 3J6, CANADA
Contact Person:	Robert A Poggie, PhD
Phone & Fax Numbers:	514-901-0796
Date of Submission:	August 23, 2023

B. 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:	Sr. VP RA / QA
Device Trade Name:	CITRELOCK® DUO
Device Common Name:	Bone Anchor, Soft Tissue Anchor, Bone Interference Screw
Classification Codes and Names:	Single/multiple component metallic bone fixation appliances and accessories (21 C.F.R. § 888.3030), and Smooth or threaded metallic bone fixation fastener (21 C.F.R. § 888.3040)
Classification Codes:	Primary code: MAI; Additional code: MBI
Classification Panel:	Orthopedic
Regulation Numbers:	Primary regulation: 21 C.F.R. § 888.3030 Additional regulation: 21 C.F.R. § 888.3040

C1. PRIMARY PREDICATE DEVICE

K220833, K200725	CITREGEN® Tendon Interference Screw (TIS) and CITRELOCK®

C2. ADDITIONAL PREDICATE DEVICE

K203334	CITREFIX™ Knotless Suture Anchor

D. Indications for Use

The CITRELOCK® DUO is intended for soft tissue reattachment, i.e., fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. More specifically:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendon Reattachment, Acromion-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist.

E. Device Description

The CITRELOCK® DUO is a two-piece design consisting of a cannulated, self-locking, CITRELOCK® implant made from CITREGEN® biomaterial coupled with an eyelet component made from PEEK. The CITRELOCK® DUO system consists of fixation devices ranging in diameter from 4 to 9 mm and lengths from 10 to 23 mm.

The purpose of this Special 510(k) Device Modification is to advise the FDA of this line extension wherein an eyelet to accommodate suture was added to the previously 510(k) cleared CITRELOCK® "twist-ribbed", cannulated, self-locking bone anchor. The CITRELOCK® DUO device utilizes the same correspondingly sized and designed primary predicate, the CITRELOCK®, with the added PEEK eyelet at the tip of the device. These two components are sterile packaged together and mounted on a Cartridge that facilitates loading onto the Inserter instrument.

The CITRELOCK® DUO is made from CITREGEN® biomaterial, which is a resorbable, homogeneous biocomposite comprised of 60 wt.-% unsintered hydroxyapatite (HA) and 40 wt.-% polyester. CITREGEN'S polymer component is a citrate-based network of completely amorphous polymer chains crosslinked together to form an elastomeric material. As water penetrates the subject device, surface erosion of the polymer phase occurs through hydrolysis of the ester bonds located between the monomers and at the crosslink sites.

The eyelet is made from polyether ether ketone (PEEK) conforming to ASTM F2026. Suture material is not provided with the device.

F. Comparison of Technological Characteristics

The CITRELOCK® DUO has the same intended and indications for use, is manufactured from the same CITREGEN® biomaterial using the same manufacturing processes, possesses similar technological characteristics, and has the same principles of operation as the primary predicate device (K200725, K220833), and the eyelet feature of the additional predicate CITREFIX™ suture anchor implant (K203334).

The subject, primary and additional predicate devices have comparable technological characteristics that include:

- Composed of the same CITREGEN® resorbable biocomposite material,
- Same diameter and length options,
- Same clinical indications for use and intended use,
- Press-fit, interference fixation designs,
- Eyelet to accommodate passing of suture,
- Implant components assembled to a cartridge as in the additional predicate (K203334),
- Provided sterile to the end user, and
- Same general surgical technique and similar reusable instrument set.

The sole difference in technological characteristics of the subject and primary predicate device is the addition of the eyelet feature to accommodate passing of suture. Verification and validation data (e.g. 'pull-out' testing) demonstrated that the subject and primary predicate devices possess statistically similar fixation strength which in turn supports substantial equivalence of devices.

Further to the above comparison of device characteristics, the subject and predicate devices are comprised of CITREGEN® biomaterial which is a homogeneous biocomposite comprised of unsintered hydroxyapatite (HA) and polyester that is bioresorbed over time. Because the design features and size options of the subject device do not present a new worst case relative to simulated soft tissue fixation in bone, the testing summarized in the DCAS table in Section 18 is sufficient for establishing substantial equivalence.

G. Performance Data

Verification and validation (V&V) activities were guided by the FDA guidance document "Premarket Notification (510(k)) Submissions for Bone Anchors", with pull-out testing performed for worst case subject devices at time-zero. The results of these tests showed the worst case subject devices (e.g. smallest diameter, shortest length) to possess similar pull out strengths relative to the primary predicate devices (K200725, K220833) thereby confirming no measurable effect of the PEEK eyelet and presence of suture at the tip and adjacent to the device.

V&V activities included adoption of previously performed validations for sterility of implants, packaging, and shipping and handling. Packaging and shelf life tests using real and accelerated time aging were performed with passing results. Bacterial endotoxin testing (BET) showed CITREGEN® based test articles to meet endotoxin limits (<20 EUs / procedure). The labeled shelf-life of the product is three years based on the original test plans cleared in K200725 and K203334.

H. Conclusion

Based on the indications for use, technological characteristics, and the V&V activities summarized herein, Acuitive Technologies, Inc. has determined that the subject CITRELOCK® DUO is substantially equivalent to the legally marketed CITRELOCK® device.