November 4, 2022

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

Re: K220833
Trade/Device Name: Citregen™ Tendon Interference Screw, Citrelock™, Citrefix™, Citrespline™ ACL, and Citrelock™ ACL
Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories; Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: October 4, 2022
Received: October 5, 2022

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 (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,

Sara S. Thompson -S

For

Laura C. Rose, 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)*
K220833

Device Name

Citregen™ Tendon Interference Screw, CitreLock™

Indications for Use *(Describe)*

The Citregen Tendon Interference Screw and CitreLock are 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K220833

Device Name

Citrefix™

Indications for Use *(Describe)*

The Acuitive Citrefix Knotless Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder foot/ ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

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

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)

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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)*
K220833

Device Name

Citrespline™ ACL, Citrelock™ ACL

Indications for Use *(Describe)*

The Citrespline ACL and Citrelock ACL are 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 for K220833

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness for the Citregen™ Tendon Interference Screw, Citrelock™, Citrefix™, Citrespline™ ACL, and Citrelock™ ACL devices.

A. 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 & Fax Number:	514-901-0796
Date of Submission:	November 3, 2022

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 R&D Operations
Device Trade Names:	Citregen™ Tendon Interference Screw, Citrelock™, Citrefix™, Citrespline™ ACL, and Citrelock™ ACL
Device Common Names:	Bone Anchor, Suture Anchor
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

K200725	Citregen Tendon Interference Screw (TIS) and Citrelock

C2. PREDICATE DEVICES

K203334	Acuitive Citrefix™ Knotless Suture Anchor
K210239	Citrespline™ and Citrelock™ ACL Implants

D. Indications for Use

Citregen™ Tendon Interference Screw, Citrelock™

The Citregen Tendon Interference Screw and Citrelock are 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.

Citrefix™

The Acuitive Citrefix Knotless Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

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

Citrespline™ ACL, Citrelock™ ACL

The Citrespline ACL and Citrelock ACL are 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 Descriptions

This 510(k) notification advises FDA of minor changes to implant specifications, revisions and additions to the class 1 instruments, and an extension of shelf life to three years per the original validation plan presented in K200725.

The subject bone anchor devices are comprised of Citregen biomaterial, which is a 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 following paragraphs describe the subject devices.

The Citregen Tendon Interference Screw and Citrelock are fixation devices ranging in diameter from 4 to 9 mm and lengths from 10 to 23 mm. There are two designs; 1) a traditional tapered, blunt threaded and cannulated screw that is screwed into the prepared bone and 2) a “twist-ribbed” cannulated, self-locking device (trade named Citrelock) that is inserted into bone. Citregen Tendon Interference Screw and Citrelock implants attach soft tissue to bone for surgical procedures in the foot/ankle, knee, shoulder, elbow, and hand/wrist. The updates to the class 1 manual instruments include minor design modifications and new reusable instruments, single-use and sterile instruments that are packaged together with an implant in a “kit” configuration and new single-use and sterile instruments to facilitate surgery.

The Citrefix is a suture anchor offered in diameters between 2.9 and 5.5 mm and lengths ranging between 12.5 and 24.0 mm, and includes an integral eyelet made of PEEK that facilitates passage of suture through the tip of the anchor. The Citrefix is implanted with reusable instruments that include size specific drills and awls for preparing the bone, and an insertion instrument for placement of the Citrefix device. Suture is not provided with the Citrefix device.

The Citrespline ACL and Citrelock ACL are bone anchor devices ranging in diameter from 7 to 12 mm in 1 mm increments, and lengths of 23, 28, and 33 mm. There are two designs for the system: 1) “twist-ribbed” cannulated, self-locking devices (Citrelock ACL) and 2) a “straight spline” style device (Citrespline ACL). Both designs have a cannula through the central axis for alignment into the surgically prepared site. Surgical placement is facilitated with a reusable set of instruments.

F. Comparison of Technological Characteristics

Acuitive Technologies subject devices and predicate implant devices (K200725, K203334, K210239) are identical in indications and intended use, size options, surgical technique, and materials. The changes made to the predicate devices include minor modifications to the tolerances of the implants and modification and addition of class 1 reusable instruments and sterile single-use instrument kits (Citrelock Xpress Instrument Kit and Citregen Tendon Sizing Kit) for the system described in K200725. The Citrelock Xpress Implant Kit includes a sterile Citrelock implant packaged together with a single use, Citrelock Xpress Instrument Kit. Engineering assessment of the updated reusable instruments and validation of performance, sterility and packaging integrity of the Citrelock Xpress Instrument Kit and Citregen Tendon Sizing Kit instruments demonstrated that the subject and predicate device instruments possess the same technological characteristics and the instruments that are provided sterile have a shelf life of 3 years.

G. Performance Data

The biocompatibility and ability to clean and sterilize the reusable instrument set was verified and validated per ISO 10993-1 and AAMI TIR30, AAMI TIR12, ISO 17664, ISO 17665, AAMI ST79, and EN 556-1.

The packaging, sterilization, shelf life, and biocompatibility of the single-use Citrelock Xpress Instrument Kit and Citregen Tendon Sizing Kit were validated per ISO 11137-1 and -2, ISO 11607-1 and -2, ASTM F1980, ASTM D4169, and ISO 10993-1. The subject devices have been validated for 3-years shelf life, real-time.

H. Conclusion

The minor changes to the specification of the implants, the modifications and additions to the reusable instruments, the addition of single use instruments and increased shelf-life for the subject devices do not raise new issues of safety or effectiveness. The information presented in this 510(k) notification demonstrates substantial equivalence of the subject and predicate devices.