February 14, 2023

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

Re: K221468
Trade/Device Name: Citregen™ Tendon Interference Screw (TIS), Citrelock™ Tendon Fixation Device, Citrespline™ and Citrelock™ ACL Implants
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: May 18, 2022
Received: May 20, 2022

Dear Dr. 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)*
K221468

Device Name

Citrespline™ and Citrelock™ ACL Implants

Indications for Use *(Describe)*

The Citrespline™ and Citrelock™ ACL Implants 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
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K221468

Device Name
Citregen™ Tendon Interference Screw (TIS) and CitreLock™ Tendon Fixation Device

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.

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510(k) SUMMARY for K221468

Acuitive Technologies CITREGEN™ Bone Anchor Devices

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 (TIS), CITRELOCK™ Tendon Fixation Device and CITRESPLINE™ and CITRELOCK™ ACL Implants.

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:	February 7, 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 R&D Operations
Device Trade Names:	CITREGEN™ Tendon Interference Screw (TIS), CITRELOCK™ Tendon Fixation Device CITRESPLINE™ and CITRELOCK™ ACL Implants
Device Common Names:	Bone Anchor
Classification Codes and Names:	Single/multiple component metallic bone fixation appliances and accessories (21 C.F.R. § 888.3030)
Classification Codes:	Primary code: MAI
Classification Panel:	Orthopedic
Regulation Numbers:	Primary regulation: 21 C.F.R. § 888.3030

C1. PRIMARY PREDICATE DEVICE

K200725	CITREGEN™ Tendon Interference Screw (TIS), CITRELOCK™ Tendon Fixation Device

C2. PREDICATE DEVICE

K210239	CITRESPLINE™ and CITRELOCK™ ACL Implants

D. Indications for Use

CITREGEN™ Tendon Interference Screw (TIS), CITRELOCK™ Tendon Fixation Device

The Citregen Tendon Interference Screw (TIS) 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.

CITRESPLINE™ and CITRELOCK™ ACL Implants

The CITRESPLINE and CITRELOCK ACL Implants 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

The primary purpose of this traditional 510(k) submission is to notify the FDA of a second option for terminal sterilization of the subject soft tissue fixation devices based on successful verification and validation testing of biocompatibility, product performance, and sterility to 10^{-6} SAL.

The subject 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 (TIS) and CITRELOCK™ Tendon Fixation Device 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 TIS and Citrelock implants attach soft tissue to bone for surgical procedures in the foot/ankle, knee, shoulder, elbow, and hand/wrist. Select single use manual instruments are packaged together with an implant in a sterile "kit" configuration (Xpress Kit). There is an additional subset of sterile single use instruments to facilitate surgery (Prep Kit). Alternatively, there is a set of reusable instruments.

THE CITRESPLINE™ and CITRELOCK™ ACL Implants 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). 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, K210239) are identical in indications and intended use, size options, surgical technique, and materials. The main purpose of this 510(k) is to notify the FDA of a second option for terminal sterilization of the subject devices using gamma radiation. The results of V&V activities in assessing biocompatibility and chemistry, product performance via pull-out strength, material properties of rate of degradation and compressive strength, and sterility assurance to 10^{-6} SAL demonstrated the gamma radiation sterilized subject Citregen devices were substantially equivalent to the EtO sterilized predicate Citregen devices.

G. Performance Data

Verification, validation, and performance testing and demonstration of substantial equivalence of subject gamma sterilized devices to predicate EtO sterilized devices is summarized as follows:

- Extractables and leachables testing of gamma sterilized devices per ISO 10993-12 and -18 showed substantial equivalence of chemistry to EtO sterilized devices.
- Sterility of subject gamma sterilized devices with a SAL of 10^{-6} was demonstrated using the ANSI/AAMI/ISO TIR 13004 (VD Max) method, ISO 11137-1, -2, -3, and ISO 11737-1, -2.
- Packaging integrity testing per ASTM F88, F1886, and F2096 met acceptance criteria for gamma sterilized test articles and determined to be substantially equivalent to devices packaged and sterilized by EtO.
- Degradation-rate and compressive strength evaluations demonstrated substantial equivalence of gamma sterilized and EtO sterilized test articles.
- Pull out testing of fixation strength of gamma sterilized 'worst-case' subject devices (smallest Citregen TIS device, 4mm diameter, 10mm long) demonstrated substantial equivalence to the same-size EtO sterilized predicate devices.

H. Conclusion

The information presented in this 510(k) notification demonstrates substantial equivalence of the subject gamma sterilized devices and predicate EtO sterilized Citregen-based devices.