February 24, 2021

Acuitive Technologies, Inc.
% Robert Poggie
President
BioVera, Inc
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7V7P2
Canada

Re: K210239
Trade/Device Name: 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: January 28, 2021
Received: January 29, 2021

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,

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)*

K210239

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.

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CITRESPLINE™ and Citrelock™ ACL Implants

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

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint Louis, Notre-Dame-de-L'lle-Perrot, QC J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone & Fax Numbers:	514-901-0796
Date of Submission:	January 28, 2021

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 Name:	CITRESPLINE™ and CITRELOCK™ ACL Implants
Device Common Name:	Fastener, Fixation, Non-Degradable, Soft Tissue
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 C.F.R. § 888.3030)
Classification Code:	MAI
Classification Panel:	Orthopedic
Regulation Number:	21 C.F.R. § 888.3030

C. PRIMARY PREDICATE DEVICE

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

D. Indications for Use

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 Description

The CITRESPLINE™ and CITRELOCK™ ACL Implants are soft tissue fixation 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) a “twist-ribbed” cannulated, self-locking device (trade names CITRELOCK ACL and CITRELOCK) and 2) a “straight spline” style device (trade name CITRESPLINE). Both designs include a cannula through the central axis to allow for alignment into the surgically prepared site. Like the predicate devices, surgical placement of the implants in bone is facilitated with a reusable set of instruments. The CITRESPLINE and CITRELOCK ACL Implants are intended to attach soft tissue to bone for procedures in the foot/ankle, knee, shoulder, elbow, and hand/wrist.

The CITRESPLINE and CITRELOCK ACL Implants are made from 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.

F. Comparison of Technological Characteristics

The CITRESPLINE and CITRELOCK ACL Implants have the same intended and indications for use, are manufactured from the same Citregen biomaterial using the same manufacturing processes, possess similar technological characteristics, and have the same principles of

operation as the primary predicate device (K200725). The subject and predicate CITREGEN-based devices have comparable technological characteristics that include:

- Composed of the same CITREGEN resorbable biocomposite material,
- Same clinical indications for use and intended use,
- Press-fit, interference fixation designs,
- Same general surgical technique and reusable instrument set, and
- Provided sterile to the end user.

The two differences in technological characteristics of the subject and predicate devices are: (1) the subject devices include sizes that are larger in diameter and longer in length, and (2) the CITRESPLINE Implant is characterized by a spline design, versus the screw and twist-ribbed designs of the primary predicate device (K200725). Verification and validation data (e.g. 'pull-out' testing) demonstrated that the CITRESPLINE and CITRELOCK ACL Implants are substantially equivalent to the CITREGEN TIS and CITRELOCK predicate 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. The design and size options of the subject CITRESPLINE and CITRELOCK ACL Implants do not present a new worst case relative to simulated soft tissue fixation in bone, which is attributed to the larger diameter and longer length of engagement in bone associated with the subject devices.

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 and after soaking in 37C PBS through 26 weeks, and pull out testing after 5,000 cycles of simulated physiological loading. The results of these tests showed the worst case subject devices (e.g. smallest diameter, shortest length) to possess similar or significantly higher pull out strengths relative to the primary predicate devices (K200725), which is attributed to the larger diameter and longer engagement length of the subject devices.

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 test articles to meet the set endotoxin limits (<20 EUs / surgical procedure). The labeled shelf-life of the product is one year based on the stability data analyzed to date.

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 CITRESPLINE and CITRELOCK ACL Implants are substantially equivalent to the legally marketed CITREGEN TIS and CITRELOCK devices.