October 7, 2020

Acuitive Technologies
% Janice Hogan
Partner
Hogan Lovells US. LLP
1735 Market Street
Philadelphia, Pennsylvania 19103

Re: K200725
Trade/Device Name: Citregen Tendon Interference Screw and Citrelock
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: September 3, 2020
Received: September 3, 2020

Dear Ms. Hogan:

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,

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: 06/30/2020 *See PRA Statement below*

510(k) Number *(if known)*

Citregen Tendon Interference Screw (TIS) and Citrelock

Device Name

K200725

Indications for Use *(Describe)*

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.

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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K200725 SUMMARY – Citregen Tendon Interference Screw and Citrelock

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

A. SUBMITTERS INFORMATION

Submitter Name:	Hogan Lovells, US LLP.
Submitter Address:	1735 Market Street, Suite 2300, Philadelphia, PA 19103
Contact Person:	Janice Hogan
Phone Number:	267-675-4600
Fax Number:	267-675-4601
Date of Submission:	October 6, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Acuitive Technologies, Inc.
Manufacturer Address:	50 Commerce Drive, Allendale, NJ 07401, USA
Contact Name:	Jaclyn Docs
Title:	Director, Quality and Regulatory Affairs
Device Trade Name:	Citregen Tendon Interference Screw and Citrelock
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
Manufacturer Name:	Acuitive Technologies, Inc.
Manufacturer Address:	50 Commerce Drive, Allendale, NJ 07401, USA
Contact Name:	Jaclyn Docs

C. PRIMARY PREDICATE DEVICE

K051726	Arthrex Tenodesis Family

D. Indications for Use

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:

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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 Citregen TIS and Citrelock are fixation devices ranging in diameter from 4 to 9 mm and lengths from 10 to 23 mm to be used with reusable instruments. There are two designs for the system: 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. The Citregen TIS and Citrelock system is intended to attach soft tissue to bone for procedures in the foot/ankle, knee, shoulder, elbow, and hand/wrist.

The Citregen TIS and Citrelock 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 Citregen TIS and Citrelock have the same intended and indications for use, as well as similar technological characteristics and principles of operation as the predicate device. The minor technological differences between the subject Citregen and predicate Arthrex devices do not raise new issues of safety or effectiveness. The data demonstrates that the Citregen TIS is substantially equivalent to the predicate device.

The subject Acuitive and predicate Arthrex soft tissue fixation devices have similar technological characteristics, including polyester-bioceramic composite materials, thread design, reusable instruments, and standard surgical techniques. The subject device is comprised of Citregen biomaterial, which is a homogeneous biocomposite comprised of unsintered hydroxyapatite (HA) and polyester that is bioresorbed over time in vivo. The predicate Arthrex device is comprised of BioComposite material that is comprised of biphasic calcium phosphate and PLDLA that also resorbs in vivo. The material differences between the Acuitive device and the predicate are the polyester, bioceramic, and weight percentage of bioceramic. The specific materials used differ from the predicate but do not raise different issues of safety or effectiveness, as confirmed by bench, biocompatibility, and animal testing.

The design options and sizes of the Citregen TIS and Citrelock facilitate use in a range of anatomical locations including the foot, ankle, knee, elbow shoulder, hand, and wrist, and are identical to that of the predicate device.

G. Performance Data

The performance characteristics of the Citregen TIS and Citrelock were established via comprehensive studies of packaging, shelf life testing, physical and chemical properties per ASTM F2902, biocompatibility tests per ISO 10993, lifecycle evaluation in GLP rabbit studies, functional performance in vitro, and functional performance in a GLP ovine model of ACL fixation. Biocompatibility evaluation included analysis of extractables and leachables data, in accordance with ISO 10993-18, as the basis for individual Toxicological Risk Assessments at three points along the implant degradation lifecycle, 0, ~25% and ~87%, in lieu of longer term in-vivo data to that same extent of degradation.

Packaging and shelf life tests using real- and accelerated time aging were performed with passing results. Bacterial endotoxin testing showed the Citregen TIS to meet the set endotoxin limits. The biocompatibility of Citregen devices was demonstrated by full panel ISO 10993 testing for a permanent implant and toxicological risk assessment, which includes the long clinical history of unsintered HA and the innate presence of citrate in bone. Biocompatibility studies performed with Citregen devices at various stages of polymer hydrolysis in a GLP rabbit bone implantation model demonstrated biocompatibility with no chronic inflammation at 4, 13, and 26 weeks per ISO 10993-6. E&L testing at various stages of polymer hydrolysis was also performed.

The Citregen TIS and Arthrex predicate devices were evaluated in a GLP functional ovine model of ACL reconstruction for 0, 3-, 6-, and 12-month time points, per ISO 10993-6.

The performance characteristics of subject and predicate devices were evaluated using imaging, histological, histomorphometry, and biomechanical data. The results of the study through 12 months demonstrated that the Citregen TIS performance was substantially equivalently to the predicate device.

The Citregen TIS and Arthrex predicate devices were further evaluated in a GLP functional ovine model of ACL reconstruction for 24-months, via imaging studies and in-life assessment.

The results of in vitro E&L analysis, toxicological risk assessment and the histology, histomorphometry, and imaging studies through 24 months in vivo demonstrated that the Citregen TIS and Citrelock performance was substantially equivalently to the predicate device.

H. Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, Acuitive Technologies, Inc. has determined that the proposed subject device is substantially equivalent to the currently marketed Arthrex predicate device. Performance testing, including in vivo data and comprehensive assessment of biocompatibility, demonstrated that the device functions as intended without raising new questions of safety or effectiveness.