March 3, 2020

AJU Pharm Co., Ltd.
℅ Peter Chung
President
Plus Global
300 Atwood St.
Pittsburgh, Pennsylvania 15213

Re: K192032
Trade/Device Name: Fixone Biocomposite Small Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: January 28, 2020
Received: February 3, 2020

Dear Peter Chung:

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.
Acting 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)*
K192032

Device Name
Fixone Biocomposite Small Anchor

Indications for Use *(Describe)*
The Fixone Biocomposite Small Anchor are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Hip: Capsular repair, Acetabular Labral repair

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.

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"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."

510(k) Summary

[K192032]

1. Applicant

1) Company : AJU Pharm Co.,Ltd.
2) Address : A-207, 697, Pangyo-ro, Seongnam-si, Gyeonggi-do, Korea
3) Tel : 82-31-765-4420
4) Fax : 82-31-602-7818
5) Prepared date : July 01, 2019
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Feb. 25, 2020
9) Prior related submissions : K171299

2. Device Information

1) Trade name : Fixone Biocomposite Small Anchor
2) Common name : Biodegradable Orthopedic Bone Screw
3) Regulation name : Single/multiple component metallic bone fixation appliances and accessories
4) Product code : MAI, MBI
5) Regulation number : 888.3080
6) Class of device : Class II
7) Panel : Orthopedic

3. The legally marketed device to which we are claiming equivalence

K140855, Arthrex SutureTak Suture Anchor

4. Device description

The Fixone Biocomposite Small Anchor is intended for reattaching soft tissue to bone with sutures. It consists of Driver, Anchor, Non-absorbable suture and needle. A needle was attached to the end of the suture so that it could penetrate the damaged soft tissue to enable it to be used for OPEN surgery without arthroscopy. The anchor is manufactured from biodegradable materials (PLGA copolymer and β-TCP). A non absorbable suture manufactured from co-braided UHMWPE and PET fibers is inserted into the anchor. The anchor is implanted using a provided driver.

This device is to be used with instrument that manufactured by Aju Pharm Co.,Ltd listed in the table below. The instruments are provided non-sterile(user must sterilization before use).

Product name	Drill bit and Drill guide with handle / Fixone.I.S-D/B300 and Fixone.I.S-D/G300
Intended use	The instruments are used to make the hole in the bone for anchor placement.
Manufacturer	AJU Pharm Co.,Ltd. / Korea
Characteristic	This device is provided as Non-sterile and Reusable device. This device is user-sterilized.
Cleaning and Sterilization process	Before use, user must proceed cleaning and sterile process. Sterilization process : Steam sterilization Temperature 132℃(270℉) / Operating time 4min / Drying 20 min

5. Intended Use :

The **Fixone Biocomposite Small Anchor** are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Hip: Capsular repair, Acetabular Labral repair

6. Performance data:

1) Bench test were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Test item	Reqirements	Results
External surface	ASTM F2502 and USP<28>	Pass
Measurement		
Insertion torque		
Fixation strength		
Tensile strength		
Extractable color		
Extraction test		
pH	The difference should be 1.5 and less.	Pass
Potassium permanganate reducing substances	The difference of the consumption of potassium permanganate should be 2.0 mL and less.	
Residue after evaporation	Record the weight of the residue should be 1.0mg and less.	
Heavy metals	Any brown color produced within 10 minutes in the tube containing the extract of the prepared sample does not exceed that in the tube containing the standard lead solution	
UV spectrum(250nm~350nm)	Maximum absorbance between 250 to 350 nm should be 0.1 and less.	
Property	When observing it with the naked eye, test solution should be clear and have no forign particles.	
Performance Testing of Fixone® Biocomposite Anchor (Pull-out test) Pull-out test by immersion time of saline solution to evaluate two bioabsorbable suture anchors. [Absorption time (soaking time) : 4 weeks, 6 weeks, 12 weeks and 26 weeks ASTM F1839-08, Standard specification for RGID Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments		Pass

2) Biocompatibility

Anchor

#	Test item	Test method / Test criteria	Test result
1	Cytotoxicity	ISO 10993-5(2009) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
2	Acute systemic toxicity test	ISO 10993-11(2009) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass
3	Pyrogen Test	ISO 10993-11 Test for systemic toxicity, pyrogen test	Pass
4	Intracutaneous(intradermal) reactivity test	ISO 10993-10(2013) Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
5	Maximization test for delayed hypersensicivity	ISO 10993-10(2013) Test for irritation and skin sensitization, Maximization test for delayed hypersensitivity	Pass
6	Bacterial revers mutation test	ISO 10993-3, Genotoxicity test OECE 471, Bacterial reverse mutation test	Pass
7	Mammalian erythrocyte micronucleus test	ISO 10993-3, Genotoxicity test OECE 471, Bacterial reverse mutation test	Pass
8	Implantation test	ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone	Pass
9	Bioabsorbable screws test	ASTM F2502 Standard specification and test methods for bioabsorbable plates and screws for internal fixation implants	Pass
10	Subchronic toxicity test	ISO 10993-11 Biological Evaluation of Medical Devices Part 11-	Pass

		Test for systemic toxicity	

Suture

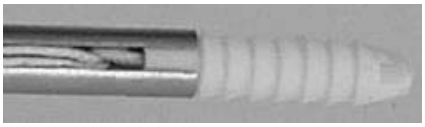
#	Test item	Test method / Test criteria	Test result
1	Cytotoxicity	ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
2	Systemic toxicity test	ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass
3	Pyrogen Test	ISO 10993-11 Test for systemic toxicity, pyrogen test	Pass
4	Intracutaneous reactivity test	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
5	Maximization sensitization	ISO 10993-10, Test for irritation and skin sensitization, Maximization test for delayed hypersensitivity	Pass
6	Genotoxicity test	ISO 10993-3, Genotoxicity test OECE 471, Bacterial reverse mutation test	Pass
8	Implantation test	ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone	Pass
9	Hemolysis test	ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	Pass

The performance tests demonstrated that Fixone Biocomposite Small Anchor performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

Manufacturer	AJU Pharm Co.,Ltd.	Arthrex Inc.	Remark
510(k) No.		K140855	N/A
Indication for use	The **Fixone Biocomposite Small Anchor** are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis **Hand/Wrist**: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction **Hip**: Capsular repair, Acetabular Labral repair	The **Arthrex SutureTak Suture Anchors** are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis **Hand/Wrist**: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction **Hip**: Capsular repair, Acetabular Labral repair	Same
Classification name	Single/multiple component metallic bone fi xation appliances and accessories	Single/multiple component metallic bone fixation appliances and accessories	Same
Trade name	Fixone Biocomposite Small Anchor	Arthrex SutureTak Suture Anchor	N/A
Model/type	9 model codes including SAB-30001a	3 model codes including 2.4mmx6.5mm Micro SutureTak	N/A

006_510(k) Summary

Manufacturer	AJU Pharm Co.,Ltd.	Arthrex Inc.	Remark
Appearance			Similar
Product configuration	Driver, Anchor, Suture and Needle	Driver, Anchor, Suture and Needle	Same
Material	PLGA + β-TCP	PLDLA + β-TCP	Different
Anchor			
Outside diameter	3.0mm	2.4mm, 3.0mm	Similar
Length of abchor	11.9mm	6.5mm, 8.5mm, 14mm	Different
Suture			
Absorbable	Non-absorbable	Non-absorbable	Same
Suture diameter	USP size #0	USP size 0 and #1	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual	Manual	Same

9. Conclusion

The device is investigated for function to compare the operation of function between Fixone Biocomposite Small Anchor and predicate devices.

Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device.

Therefore, it is concluded that Fixone Biocomposite Small Anchor is substantially equivalent to the legally marketed predicate device.