June 9, 2023

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

Re: K230892
Trade/Device Name: Fixone Biocomposite 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
Dated: March 31, 2023
Received: March 31, 2023

Dear Mr. 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,

Sara S. Thompson -S

For

Jesse Muir, 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)*
K230892

Device Name
Fixone Biocomposite Anchor

Indications for Use *(Describe)*
The Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee 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;
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction.

The following indications are for the S and SL type anchors only:

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
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.

510(k) Summary

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) Preparation date : Mar. 31, 2023
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : June 8, 2023
9) Submission type : Special
10) Prior related submissions : K171299, K192484, K192032, K203523
11) Submission Number : K230892

2. Device Information

1) Trade name : Fixone Biocomposite Anchor
2) Common name : Fastener, Fixation, Biodegradable, Soft Tissue
3) Regulation name : Single/multiple component metallic bone fixation appliances and accessories.
4) Product code : MAI
5) Regulation number : 888.3030
6) Class of device : Class II
7) Panel : Orthopedic

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

K203523, Aju Pharm Co., Ltd. / Fixone hybrid knotless anchor (Only for UHMWPE suture)

Reference devices
K171299, Aju Pharm Co., Ltd. / Fixone Biocomposite Anchor
K192484, Aju Pharm Co., Ltd. / Fixone Biocomposite Anchor (Special submission of K171299)
K192032, Aju Pharm Co., Ltd. / Fixone Biocomposite Small Anchor

4. Device description

The Fixone Biocomposite Anchor is intended for reattaching soft tissue to bone with sutures. The anchor is manufactured from biodegradable materials (PLGA copolymer and β-TCP). A nonabsorbable UHMWPE suture is inserted into the anchor. The anchor is implanted using a provided driver.

B,N,BN type(Knotted suture anchors) are 'screw-in' anchors used alone or in combination with Kc,KcN type(Knotless suture anchors) for soft-tissue repair.

Kc,KcN type(Knotless suture anchor) are used for a soft-tissue repair in combination with the B,N,BN type.

SL type 'push-in' anchors that are ideal for soft-tissue repair in narrow or deep areas.

S type are 'push-in' anchors that are ideal for soft-tissue repair in the foot, ankle, hand and wrist

The Fixone Biocomposite Anchor consists of cannulated anchors with an eyelet. They are pre-loaded on an insertion device. The Fixone Biocomposite Anchor is intended to provide secure reattachment of the soft tissue to bone.

Devices are provided sterile. Single use only.

5. Intended Use :

The Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee 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;
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction.

The following indications are for the S and SL type anchors only:

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
Hip: Capsular repair, Acetabular Labral repair

6. Predicate device comparison table

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
510(k) No.	K171299	K192032	K192484	K213008	N/A

Indication for use	**The Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee 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; **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.	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 Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee 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; **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.	**The Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee 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; **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction. **The following indications are for the S and SL type anchors only:** **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 **Hip**: Capsular repair, Acetabular Labral repair	Similar
Classification name	Fastener, Fixation, Biodegradable, Soft Tissue	Fastener, Fixation, Biodegradable, Soft Tissue	Fastener, Fixation, Biodegradable, Soft Tissue	Fastener, Fixation, Biodegradable, Soft Tissue	Same
Trade name	Fixone Biocomposite Anchor	Fixone Biocomposite Small Anchor	Fixone Biocomposite Anchor	Fixone Biocomposite Anchor	Same

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
Model/type	80 model codes including BAB-45001a	9 model codes including SAB-30001a	161 model codes including BAB-45001a	211 model codes including BAB-45002ah	N/A
Product configuration	Driver Anchor Suture	Driver Anchor Suture	Driver Anchor Suture	Driver Anchor Suture	Same
Material	PLGA(70%) + β-TCP(30%)	PLGA(70%) + β-TCP(30%)	PLGA(70%) + β-TCP(30%)	PLGA(70%) + β-TCP(30%)	Same
Anchor					
Outside diameter	4.5mm/4.75mm/5.5mm/5.75mm/6.5mm	3.0mm	3.0mm/4.5mm/4.75mm 5.5mm/5.75mm/6.5mm	3.0mm/4.5mm/4.75mm 5.5mm/5.75mm/6.5mm	Similar
Length of anchor	14.6mm/15mm/15.7mm/ 16mm/16.8mm	11.9mm	11.9mm/14.6mm/15mm/ 15.7mm/16mm/16.5mm/ 16.8mm	11.9mm/14.6mm/15mm/ 15.7mm/16mm/16.5mm/ 16.8mm/17mm/17.7mm	Similar
Fixation mechanism	Anchor holds soft tissue and suture. Anchor and suture could endure the tension of moving during degradation of anchor.	Anchor holds soft tissue and suture. Anchor and suture could endure the tension of moving during degradation of anchor.	Anchor holds soft tissue and suture. Anchor and suture could endure the tension of moving during degradation of anchor.	Anchor holds soft tissue and suture. Anchor and suture could endure the tension of moving during degradation of anchor.	Same
Inner diameter	Same as subject	Same as subject	Same as subject	Same as predicate	Same
Degradation	Average 15% to 4 weeks	Average 15% to 4 weeks	Average 15% to 4 weeks	Average 15% to 4 weeks	Same
Suture					
Absorbable	Non-absorbable	Non-absorbable	Non-absorbable	Non-absorbable	Same
Suture diameter	0.50~0.599 (USP size 2)	0.35~0.399 (USP size 0)	0.50~0.599 (USP size 2)	0.35~0.399 (USP size 0) 0.50~0.599 (USP size 2)	Similar
Material	Polyethylene	Polyethylene	Polyethylene	Polyethylene (UHMWPE)	Same
Colorant	Blue / Green / Violet	Blue / Green / Violet	Blue / Green / Violet	Blue / Green / Violet / Black	Similar
Sterilization	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	Same
Biodegradable	No	No	No	No	Same
Principle of operation	Manual	Manual	Manual	Manual	Same
Shelf-life	5 years	5 years	5 years	5 years	Same
Inserter configuration	Shaft that holds the anchor from inside with suture	Shaft that holds the anchor from inside with suture	Shaft that holds the anchor from inside with suture	Shaft that holds the anchor from inside with suture	Same

K192032, Fixone Biocomposite Small Anchor could be used in smaller surgery spot like hand, wrist and hip. Differences of intended use was just come from device size.
The differences between predicate and subject device which could effect the performance of device is thread and suture.

Thread – Added new performance test data of dual-threaded anchors. KcN type is from the Kc type. KcN type anchor has same design with Kc type anchor except only the thread. BN type anchor is from N type anchor. The eyelet part of BN type is different with the eyelet of N type anchor. BN type has same design with N type anchor except only the eyelet design.

Suture – Added new performance test data of only UHMWPE suture. (Previously cleared in K203523)

These differences could be explained with new test report and also could be explained by predicate devices because all of these predicate devices were made with same manufacturing process of subject device.

7. Performance data:

Bench test were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues, shelf-life testing, pyrogenicity testing and endotoxin monitoring. The tests demonstrated that the device performs in a substantially equivalent manner to the prior related devices.

8. Conclusion

The device is investigated for function to compare the operation of function between Fixone Biocomposite Anchor and prior related 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 Anchor is substantially equivalent to the legally marketed predicate device.