March 11, 2020

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

Re: K192484
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: February 5, 2020
Received: February 11, 2020

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,

for

Laura 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)*
K192484

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.

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

[K192484]

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 : Sep. 01, 2019
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Mar. 11, 2020
9) Submission type : Traditional
10) Prior related submissions : K171299

2. Device Information

1) Trade name : Fixone Biocomposite Anchor
2) Common name : Biodegradable Orthopedic Bone Screw
3) Regulation name : Fastener, Screw, Fixation, Bone, Suture
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

K171299, Aju Pharm Co., Ltd. / Fixone Biocomposite 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 nonresorbable suture manufactured from cobraided UHMWPE and PET fibers is inserted into the anchor. The anchor is implanted using a provided driver.

This device is could used with instrument that manufactured by Aju Pharm Co.,Ltd. It is consist of 18 models. It provide non-sterile (user must sterilization before use).

Product name	Instrument / 20 model codes including Fixone.I.B-A/T450a
Intended use	The instrument of make the hole in the bone.
Manufacturer	AJU Pharm Co.,Ltd. / Korea
Characteristic	This device is provided as Non-sterile and Reusable device. This device is provided non-sterile. This device is user-sterilized.
Sterilization method	Autoclave / 132℃ / 4min / 20 min dry

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.

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	Requirements	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 comparision test of FIXONE and Arthrex suture anchor		
Insertion force	ASTM F2502	Pass
Insertion torque		
Pull-out test		
Fatigue test	The anchor shall be inserted into the pilot hole. Apply the load 50% of Pull-out test(offset 10%, Sine shape) - 30° (worst case)	
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) : 5min, 1hr, 4hr, 8hr, 12hr, 24hr ASTM F1839-08, Standard specification for RGID Polyurethane Foam for Use as a Standard Mate rial for Testing Orthopaedic Devices and Instruments		Pass
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
Shelf life testing To make shelf life time, my company set Real-time equivalent (RTE) and Accelerated aging temperature, Taa as per AAMI TIR17 and ASTM F 1980-02. Aging temperature: 55±2℃, aging time: 225 days		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(intraderm al) 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 hypersensitivity	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-Test for systemic toxicity	Pass

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

Final product

1	LAL test	USP 38 NF 33 <85> Bacterial Endotoxin test “Gel clot method”	Pass

LAL test was performed in final product that consist of anchor and suture.

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

7. Predicate device comparison table

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
510(k) No.	K171299		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, UInar 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, UInar or Radial Collateral Ligament Reconstruction.	Same
Classification name	Fastener, Screw, Fixation, Bone, Suture	Fastener, Screw, Fixation, Bone, Suture	Same

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
Trade name	Fixone Biocomposite Anchor	Fixone Biocomposite Anchor	Same
Model/type	80 model codes including BAB-45001a	161 model codes including BAB-45001a	N/A
Product configuration	Driver Anchor Suture	Driver Anchor Suture	Same
Material	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/4.5mm/4.75mm 5.5mm/5.75mm/6.5mm	Similar
Length of abchor	14.6mm/15mm/15.7mm/16mm/16.8mm	11.9mm/14.6mm/15mm/15.7mm 16mm/16.5mm/16.8mm	Similar
Suture			
Absorbable	Non-absorbable	Non-absorbable	Same
Suture diameter	0.50~0.599 (USP size 2)	0.50~0.599 (USP size 2)	Same
Material	Polyethylene	Polyethylene	Same
Sterilization	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual	Manual	Same
Shelf-life	5 years	5 years	Same

9. Conclusion

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