DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 24, 2017

Re: K171299
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: July 10, 2017
Received: July 17, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171299

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: Rotor 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

[as required by 807.92(c)]

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 : Jul. 4, 2016
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Jul. 11, 2016

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

K043337, Arthrex, Inc. Bio-Corkscrew Suture Anchor
K101679, Arthrex, Inc. PushLock Anchors
K073412, Depuy Mitek, Healix BR 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 / 18 model codes including Fixone.I.B-A/T450a
Model name	Fixone.I.B-A/T450a, Fixone.I.B-A/T475a, Fixone.I.B-A/T500a, Fixone.I.B-A/T525a, Fixone.I.B-A/T550a, Fixone.I.B-A/T575a, Fixone.I.B-A/T600a, Fixone.I.B-A/T625a, Fixone.I.B-A/T650a, Fixone.I.B-Awl450a, Fixone.I.B-Awl475a, Fixone.I.B-Awl500a ,Fixone.I.B-Awl525a, Fixone.I.B-Awl550a, Fixone.I.B-Awl575a, Fixone.I.B-Awl600a, Fixone.I.B-Awl625a, Fixone.I.B-Awl650a
Intended use	The instrument of make the hole in the bone.
Manufacturer	Ajumedical / Korea
Sterilization	Non-sterile
Sterilization method	Autoclave / 134℃/ 20 min

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: Rotor 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	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.	

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 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-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

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

7. Predicate device comparison table

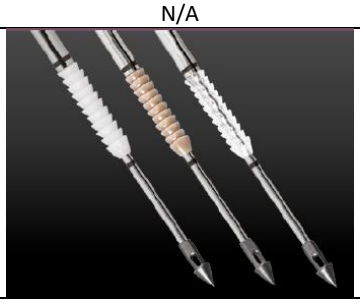
1) B-type and K-type

Manufacturer	AJU Pharm Co.,Ltd.	Depuy Mitek	Remark
510(k) No.	K171299	K073412	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:** Rotor 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.	**Shoulder:** Rotor 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
Trade name	Fixone Biocomposite Anchor	Healix BR Anchor	N/A
Model/type	80 model codes including BAB-45001a	5 model codes including 4.5 Healix BR Anchor	N/A
Appearance			Similar
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	4.5mm/5.5mm/6.5mm	Similar
Length of abchor	14.6mm/15mm/15.7mm/16mm/16.8mm	Not known	N/A
Suture			
Absorbable	Non-absorbable	Non-absorbable	Same
Suture diameter	0.50~0.599 (USP size 2)	0.50~0.599 (USP size 2)	Same

Manufacturer	AJU Pharm Co.,Ltd.	Depuy Mitek	Remark
Material	Polyethylene	Polyethylene	Same
Sterilization	EO Gas sterilization According to ISO 11135: 2007	EO Gas sterilization According to ISO 11135: 2007	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual	Manual	Same
Shelf-life	5 years	N/A	N/A

Manufacturer	AJU Pharm Co.,Ltd.	Arthrex, Inc.	Remark
510(k) No.	K171299	K043337	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:** Rotor 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 Arthrex Bio-Corkscrew Suture Anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis.	Similar
Classification name	Fastener, Screw, Fixation, Bone, Suture	Fastener, Screw, Fixation, Bone, Suture	Same
Trade name	Fixone Biocomposite Anchor	Bio-Corkscrew Suture Anchor	N/A
Model/type	80 model codes including BAB-45001a	N/A	N/A
Appearance			Similar
Product configuration	Driver Anchor Suture	Driver Anchor Suture	Same
Material	PLGA + β-TCP	PLLA + B-TRICALCIUM PHOSPHATE	Similar
Anchor			
Outside diameter	4.5mm/4.75mm/5.5mm/5.75mm/6.5mm	4.5mm/4.75mm/5.5mm/5.75mm/6.5mm	Same
Length of abchor	14.6mm/15mm/15.7mm/16mm/16.8mm	15mm/16mm	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: 2007	EO Gas sterilization According to ISO 11135: 2007	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual	Manual	Same
Shelf-life	5 years	N/A	N/A

2) KC-type

Manufacturer	AJU Pharm Co.,Ltd.	Arthrex, Inc.	Remark
510(k) No.	K171299	K101679	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:** Rotor 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.	Intended to be used for sutures or tissuer fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, hip	Similar
Classification name	Fastener, Screw, Fixation, Bone, Suture	Fastener, Screw, Fixation, Bone, Suture	Same
Trade name	Fixone Biocomposite Anchor	Arthrex PushLock Anchors	N/A
Model/type	80 model codes including BAB-45001a	N/A	N/A
Appearance			Similar
Product configuration	Driver Anchor Suture Clip	Driver Anchor Suture	Same Same Same Different
Material	PLGA + β-TCP	PLLA + B-TRICALCIUM PHOSPHATE	Similar
Anchor			
Outside diameter	4.5mm/4.75mm/5.5mm/5.75mm 6.0mm/6.5mm	3.5mm/4.5mm/4.75mm/5.5mm	Similar
Length of abchor	16.7mm/17.2mm/17.7mm	15.0mm/19.1mm/19.5mm/20.0mm 24.0mm/24.5mm/28.0mm	Similar
Sterilization	EO Gas sterilization According to ISO 11135: 2007	EO Gas sterilization According to ISO 11135: 2007	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual	Manual	Same
Shelf-life	5 years	N/A	N/A

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.