December 25, 2021

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

Re: K203523
Trade/Device Name: Fixone Hybrid Knotless 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: November 19, 2021
Received: November 23, 2021

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,

for

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K203523

Device Name
Fixone Hybrid Knotless Anchor

Indications for Use *(Describe)*
The Fixone Hybrid Knotless Anchor is 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 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) Prepared date : Nov. 09. 2020
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Dec. 22. 2021
9) Submission type : Traditional
10) Prior related submissions : K192484 Kc type anchor

**2. Device Information**

1) Trade name : Fixone Hybrid knotless 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, MBI
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**

K192484, Aju Pharm Co., Ltd. / Fixone Biocomposite Anchor (Especially Kc Type)

**4. Device description**

The Fixone Hybrid Knotless Anchor is intended for reattaching soft tissue to bone with sutures. The anchor is manufactured from biodegradable materials (PLGA copolymer and β-TCP) and nonabsorbable PEEK tip. A nonabsorbable suture manufactured from cobraided UHMWPE only or 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 11 models. It provide non-sterile (user must sterilization before use).

| | |
|---|---|
| **Product name** | Instrument / 11 model codes including |
| **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.<br>This device is provided non-sterile. This device is user-sterilized. |
| **Sterilization method** | Autoclave / 132℃ / 4min / 20 min dry |

**5. Intended Use :**

**The Fixone Hybrid Knotless Anchor is 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 | According to test methods of ASTM F2502 and USP<28><br><br>Surface and measurement : Using vernier caliper, micrometer or a tape measure, should be within 5% of the dimension specified in specifications.<br><br>Insertion torque : Drive the specimen into the test block(ASTM F1839) at a rate of 1r/min. Should not be less than 0.15Nm.<br><br>Fixation : Apply a compressive load to the test specimen at a rate of 5mm/min. Should not be less than 100N.<br><br>Tensile strength : measuring 10 suture threads with stretching. Should not be less than 34.5N<br><br>Torsional test : Apply torsional load to the test specimen at a rate of 5r/min. This maximum torque should not be less than insertion torque.<br><br>Fixation anchor could endure movement of tissues and bones.<br><br>Arthrex did pull out and cyclic pull-out testing to support device performance. | Pass |
| Measurement | | |
| Insertion torque | | |
| Fixation strength | | |
| Tensile strength | | |
| Torsional Test | | |
| **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 foreign particles. | |
| Pyrogen | Material-mediated pyrogens<br><br>ISO10993-11, USP39<151> | Pass |

| | | |
|---|---|---|
| **Shelf life testing**<br><br>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.<br><br>Aging temperature: 55±2℃, aging time: 229 days | | Pass |
| **Shelf life testing(Real-time)**<br><br>**This aims to verify that this product is valid for 5 years (60 months) by testing physicochemical changes and packaging of the materials and the product at six times points before real time aging (0 year), middle real time aging (1 year, 2 years, 3 years, 4years) and after real time aging (5 years) on the evaluation of validity and safety for medical appliances by ISO 11607-1:2006, ISO 11607-2:2006.** | | Pass |
| EO sterilization Validation<br><br>(EO residual test in EO sterilization Validation report) | ISO11135(2014) | 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 | Maximization test for delayed hypersensitivity | ISO 10993-10, Tests for irritation and skin sensitization, Maximization test for delayed hypersensitivity | Pass |
| 3 | Intracutaneous reactivity | ISO 10993-10, Tests for irritation and skin sensitization, Intracutaneous(Intradermal)Reactivity Test | Pass |
| 4 | Acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Acute Systemic toxicity | Pass |
| 5 | Material-mediated Pyrogen | ISO 10993-11 Test for systemic toxicity, pyrogen test | Pass |
| 6 | Sub acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Systemic toxicity | Pass |
| 7 | Bacterial reverse mutation test | ISO 10993-3, Genotoxicity test OECD 471, Bacterial reverse mutation test | Pass |
| 8 | Mammalian erythrocyte micronucleus test | ISO 10993-3, Genotoxicity test OECD 474, Mammalian erythrocyte micronucleus test | Pass |
| 9 | Implantation test | ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone | 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 | Maximization test for delayed hypersensitivity | ISO 10993-10, Tests for irritation and skin sensitization, Maximization test for delayed hypersensitivity | Pass |
| 3 | Intracutaneous reactivity | ISO 10993-10, Tests for irritation and skin sensitization, Intracutaneous (Intradermal)Reactivity Test | Pass |
| 4 | Acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Acute Systemic toxicity | Pass |
| 5 | Material-mediated Pyrogen | ISO 10993-11 Test for systemic toxicity, pyrogen test | Pass |
| 6 | Sub acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Systemic toxicity | Pass |
| 7 | Bacterial reverse mutation test | ISO 10993-3, Genotoxicity test OECD 471, Bacterial reverse mutation test | Pass |
| 8 | Mammalian erythrocyte micronucleus test | ISO 10993-3, Genotoxicity test OECD 474, Bacterial reverse mutation test | Pass |
| 9 | Implantation test | ISO 10993-6, Tests for local effects after implantation(4weeks) | Pass |
| | | ISO 10993-6, Tests for local effects after implantation(12weeks) | Pass |
| 10 | Biological risk assessment | This assessment and evaluation plan focuses on the requirements of ISO 10993-1:2009 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, EN ISO 14971:2012 - Medical devices – Application of risk management to medical devices, FDA General Program Memorandum #G95-1, Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the European Union Medical Device Directive 93/42/EEC.1,2,3,4 It examines the components used in the device, information on the device materials in the literature, and the history of safe and effective use of the device materials in humans. | - |

Tip

| # | 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 | Maximization test for delayed hypersensitivity | ISO 10993-10, Tests for irritation and skin sensitization, Maximization test for delayed hypersensitivity | Pass |
| | | | Pass |
| 3 | Intracutaneous reactivity | ISO 10993-10, Tests for irritation and skin sensitization, Intracutaneous(Intradermal)Reactivity Test | Pass |
| 4 | Acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Acute Systemic toxicity | Pass |
| 5 | Material-mediated Pyrogen | ISO 10993-11 Test for systemic toxicity, pyrogen test | Pass |
| 6 | Sub acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Systemic toxicity | Pass |
| 7 | Bacterial reverse mutation test | ISO 10993-3, Genotoxicity test OECD 471, Bacterial reverse mutation test | Pass |
| 8 | Mammalian erythrocyte micronucleus test | ISO 10993-3, Genotoxicity test OECD 474, Bacterial reverse mutation test | Pass |
| 9 | Implantation test | ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone | Pass |

**Suture(White(B), Black(90%)/White(10%), Black(50%)/White(50%), Black(10%)/White(90%), Black(100%))**
**(Newly added information)**

| # | 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 | Maximization test for delayed hypersensitivity | ISO 10993-10, Tests for irritation and skin sensitization, Maximization test for delayed hypersensitivity | Pass |
| 3 | Intracutaneous reactivity | ISO 10993-10, Tests for irritation and skin sensitization, Intracutaneous (Intradermal)Reactivity Test | Pass |
| 4 | Acute Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Acute Systemic toxicity | Pass |
| 5 | Material-mediated Pyrogen | ISO 10993-11 Test for systemic toxicity, pyrogen test | Pass |
| 6 | Sub chronic Systemic toxicity | ISO 10993-11 Test for systemic toxicity, Sub chronic Systemic toxicity | Pass |

| | | | |
|---|---|---|---|
| 7 | Bacterial reverse mutation test | ISO 10993-3, Genotoxicity test OECD 471, Bacterial reverse mutation test | Pass |
| 8 | Mammalian erythrocyte micronucleus test | ISO 10993-2, Genotoxicity test OECD 474, Mammalian erythrocyte micronucleus test | Pass |
| 9 | Implantation test | ISO 10993-6, Tests for local effects after implantation(4weeks) | Pass |
| | | ISO 10993-6, Tests for local effects after implantation(12weeks) | Pass |

**Driver shaft (Stainless steel 304)**

| # | 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 | Intracutaneous reactivity test | ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | Pass |
| 3 | Maximization sensitization | ISO 10993-10, Test for irritation and skin sensitization, Maximization test for delayed hypersensitivity | Pass |

Endotoxin test

| # | Test item | Test method / Test criteria | Test result |
|---|---|---|---|
| 1 | Endotoxin | USP 43 <85>, Bacterial endotoxin test (LAL) | Pass |

Endotoxin level and EO sterilization validation will be monitored In an alternative plan to batch testing.

The performance tests demonstrated that Fixone Hybrid Knotless 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. | K192484 | K203523 | 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:**<br><br>**Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;<br><br>**Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;<br><br>**Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; | **The Fixone Hybrid Knotless Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee and elbow in the following procedures:**<br><br>**Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;<br><br>**Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;<br><br>**Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, | Same |

| Manufacturer | AJU Pharm Co.,Ltd. | AJU Pharm Co.,Ltd. | Remark |
|---|---|---|---|
| | **Elbow:** Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction. | lliotibial Band Tenodesis;<br>**Elbow:** Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction. | |
| Classification name | Fastener, Fixation, Biodegradable, Soft tissue | Fastener, Fixation, Biodegradable, Soft tissue | Same |
| Trade name | Fixone Biocomposite Anchor | Fixone Hybrid Knotless Anchor | |
| Model/type | 161 model codes including BAB-45001a | 8 models include KAP-47501ca | N/A |
| Product configuration | Driver<br>Anchor<br>Suture | Driver<br>Anchor<br>Suture | Same |
| Material | PLLA + β-TCP | PLGA + β-TCP<br>PEEK | PEEK |
| **Anchor** | | | |
| Outside diameter | 3.0mm/4.5mm/4.75mm<br>5.5mm/5.75mm/6.5mm | 4.75mm / 5.5mm | Same (Included) |
| Length of anchor | 11.9mm/14.6mm/15mm/15.7mm<br>16mm/16.5mm/16.8mm | 14.7mm / 15 mm | Same (Included) |
| Length of tip | 10.5mm | 10.5mm | Same |
| **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 | UHMWPE | UHMWPE+PET (Colored suture)<br>UHMWPE (Black, White) | Similar |
| Sterilization | EO Gas sterilization<br>According to ISO 11135: 2014 | EO Gas sterilization<br>According to ISO 11135: 2014 | Same |
| Biodegradable | Yes | Yes | Same |
| Principle of operation | Manual | Manual | Same |
| Shelf-life | 5 years | 5 years | Same |

PEEK : This is the only different part between subject and predicate device.

**8. Conclusion**

The device is investigated for function to compare the operation of function between Fixone Hybrid Knotless Anchor

and predicate devices.

The subject device was made very similarly with the kc type anchor in K192484. The material of tip is the only different thing. Biodegradable material, PLGA + β-TCP was used in the tip of KC type. Non-biodegradable material, PEEK was used in the tip of subject device. Other materials, mechanical properties, appearance and using methods are all same.

The tip of KP type of PEEK is non-biodegradable material that compared to PLGA + β-TCP.

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 Hybrid Knotless Anchor is substantially equivalent to the legally marketed predicate device.