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

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
Indications for Use

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, Iliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, Ulnar 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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

*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.*
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: 888.30
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).

<table>
<thead>
<tr>
<th>Product name</th>
<th>Instrument / 18 model codes including Fixone.I.B-A/T450a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td>The instrument of make the hole in the bone.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Ajumedical / Korea</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Non-sterile</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>Autoclave / 134°C / 20 min</td>
</tr>
</tbody>
</table>

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, Iliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, Ulnar 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.

<table>
<thead>
<tr>
<th>Test item</th>
<th>Requirements</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>External surface</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement</td>
<td>ASTM F2502 and USP&lt;28&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Insertion torque</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixation strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tensile strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extractable color</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Extraction test**

<table>
<thead>
<tr>
<th>Property</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>The difference should be 1.5 and less.</td>
</tr>
<tr>
<td>Potassium permanganate reducing substances</td>
<td>The difference of the consumption of potassium permanganate should be 2.0 mL and less.</td>
</tr>
<tr>
<td>Residue after evaporation</td>
<td>Record the weight of the residue should be 1.0mg and less.</td>
</tr>
</tbody>
</table>

| 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 | Pass |
| UV spectrum(250nm~350nm)                         | Maximum absorbance between 250 to 350 nm should be 0.1 and less. | Pass |

2) Biocompatibility

**Anchor**

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

**Suture**

<table>
<thead>
<tr>
<th>#</th>
<th>Test item</th>
<th>Test method / Test criteria</th>
<th>Test result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cytotoxicity</td>
<td>ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity</td>
<td>Pass</td>
</tr>
<tr>
<td>2</td>
<td>Systemic toxicity test</td>
<td>ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity</td>
<td>Pass</td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>A&amp;U Pharm Co.,Ltd.</th>
<th>Depuy Mitek</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) No.</td>
<td>K171299</td>
<td>K073412</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**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.

**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.

**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**

<table>
<thead>
<tr>
<th>Product configuration</th>
<th>Fixone Biocomposite Anchor</th>
<th>Healix BR Anchor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driver</td>
<td>Anchor</td>
<td>Anchor</td>
</tr>
<tr>
<td>Anchor</td>
<td>Suture</td>
<td>Suture</td>
</tr>
<tr>
<td>Material</td>
<td>PLGA(70%) + β-TCP(30%)</td>
<td>PLGA(70%) + β-TCP(30%)</td>
</tr>
</tbody>
</table>

**Same**

**Anchor**

| Outside diameter      | 4.5mm/4.75mm/5.5mm/5.75mm/6.5mm | 4.5mm/5.5mm/6.5mm |

**Similar**

| Length of anchor      | 14.6mm/15mm/15.7mm/16mm/16.8mm | Not known |

**N/A**

**Suture**

| Absorbable            | Non-absorbable              |

**Same**

| Suture diameter       | 0.50~0.599 (USP size 2)    | 0.50~0.599 (USP size 2) |

**Same**
### Manufacturer

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>AJU Pharm Co., Ltd.</th>
<th>Depuy Mitek</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Polyethylene</td>
<td>Polyethylene</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization</td>
<td>EO Gas sterilization</td>
<td>EO Gas sterilization</td>
<td>Same</td>
</tr>
<tr>
<td>Biodegradable</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>Manual</td>
<td>Manual</td>
<td>Same</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>5 years</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Manufacturer

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>AJU Pharm Co., Ltd.</th>
<th>Arthrex, Inc.</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) No.</td>
<td>K171299</td>
<td>K043337</td>
<td>N/A</td>
</tr>
<tr>
<td>Indication for use</td>
<td>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: <strong>Shoulder</strong>: Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction; <strong>Foot/Ankle</strong>: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; <strong>Knee</strong>: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; <strong>Elbow</strong>: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.</td>
<td>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.</td>
<td>Similar</td>
</tr>
<tr>
<td>Classification name</td>
<td>Fastener, Screw, Fixation, Bone, Suture</td>
<td>Fastener, Screw, Fixation, Bone, Suture</td>
<td>Same</td>
</tr>
<tr>
<td>Trade name</td>
<td>Fixone Biocomposite Anchor</td>
<td>Bio-Corkscrew Suture Anchor</td>
<td>N/A</td>
</tr>
<tr>
<td>Model/type</td>
<td>80 model codes including BAB-45001a</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Appearance</td>
<td>Similar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product configuration</td>
<td>Driver Anchor Suture</td>
<td>Driver Anchor Suture</td>
<td>Same</td>
</tr>
<tr>
<td>Material</td>
<td>PLGA + β-TCP</td>
<td>PLLA + B-TRICALCIUM PHOSPHATE</td>
<td>Similar</td>
</tr>
</tbody>
</table>

### Anchor

<table>
<thead>
<tr>
<th>Anchor</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside diameter</td>
<td>4.5mm/4.75mm/5.5mm/5.75mm/6.5mm</td>
</tr>
<tr>
<td>Length of anchor</td>
<td>14.6mm/15mm/15.7mm/16mm/16.8mm</td>
</tr>
</tbody>
</table>

### Suture

<table>
<thead>
<tr>
<th>Suture</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorbable</td>
<td>Non-absorbable</td>
</tr>
<tr>
<td>Suture diameter</td>
<td>0.50~0.599 (USP size 2)</td>
</tr>
<tr>
<td>Material</td>
<td>Polyethylene</td>
</tr>
<tr>
<td>Biodegradable</td>
<td>Yes</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>Manual</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>5 years</td>
</tr>
</tbody>
</table>
2) KC-type

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>AJU Pharm Co., Ltd.</th>
<th>Arthrex, Inc.</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) No.</td>
<td>K171299</td>
<td>K101679</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**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 Tendon Repair, Acromio-Clavicular Separation Repair, Deltoit 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.

Intended to be used for sutures or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, hip

**Classification name**

Fastener, Screw, Fixation, Bone, Suture

**Trade name**

Fixone Biocomposite Anchor

**Model/type**

80 model codes including BAB-45001a

**Appearance**

Similar

**Product configuration**

Driver
Anchor
Suture
Clip

Driver
Anchor
Suture

Same
Same
Same

**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 anchor**

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

**Principal of operation**

Manual

Manual

Same

**Shelf-life**

5 years

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.