March 23, 2023

AJU Pharm Co., Ltd.
% Peter Chung
300, Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K222423
Trade/Device Name: Fixone All Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 21, 2023
Received: February 21, 2023

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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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)*
K222423

Device Name
Fixone All Suture Anchor

Indications for Use *(Describe)*
The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Fixone All Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

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.

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."

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 : March 22, 2023
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : August 08, 2022

2. Device Information

1) Trade name : Fixone All Suture Anchor
2) Common name : Non-absorbable Suture Anchor
3) Regulation name : Fastener, Fixation, Nondegradable, Soft tissue
4) Product code : MBI
5) Regulation number : 888.3040
6) Class of device : Class II
7) Panel : Orthopedic

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

K192709 AJU Pharm Co., Ltd. / Fixone All Suture Anchor

Reference Devices

K192032 AJU Pharm Co., Ltd. / Fixone Biocomposite Small Anchor
K133224 CONMED Co. / Y-Knot RC All-Suture Anchor
K110145 Biomet, Inc. / Biomet Sports Medicine Juggerknot Soft Anchor

4. Device description

Fixone All suture anchor consists of one “fix Suture” and one,two or three non-absorbable Sutures. The non-absorbable suture is manufactured from UHMWPE. They are pre-loaded on a handled insertion device. This device is provided sterile, for single use only. This device is medical device. Prescription use only.

The color additive copper-phthalocyanine blue, color additive D&C green 6, color additive D&C violet 2 and color additive D&C black 4 are according to FDA regulations and it is approved for use in medical applications (§74.3045 – FDA), (§74.3206 –FDA), (§74.1602 –FDA) and (§74.3054 – FDA) respectively.”

5. Indications for Use :

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Fixone All Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

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.

Anchor

Test item	Requirements	Results
Insertion Strength	Insert each anchor with 5mm/min rate into 10pcf/40pcf combined urethane block.	Pass
Pull-out	Pull out each anchor with 5mm/min rate from 10pcf/40pcf combined urethane block.	
Fatique test	Pull out each anchor with 20N to 60N cycle loading and 1Hz/40,000 cycles from 10pcf/40pcf combined urethane block.	

FAS-1652802iw model was used for this test. This test report shows the performance of Js type all suture anchor that has smaller length of flat suture. This performance test was done with FDA cleared device (K133224).

Anchor

Test item	Requirements	Results
Pull-out	Pull out each anchor with 5mm/min rate from 10pcf/40pcf combined urethane block.	Pass
Fatique test	Pull out each anchor with 20N to 60N cycle loading and 1Hz/40,000 cycles from 10pcf/40pcf combined urethane block.	

FAM-7615802fg model was used for this test. This test report shows the performance of JM type all suture anchor that has smaller length of flat suture. This performance test was done with FDA cleared device (K110145).

Suture (USP 0, UHMWPE)

Test item	Requirements	Results
Appearance	The test article shall be no damage to the appearance in visual inspection.	Pass
Length	The length of suture was measured while the strand is laid out smooth, without tension, on a plane surface: the length of the strand is not less than 95.0 percent of 750mm.	
Tensile Strength	For USP 0 size suture, tensile strength must be larger than 2.16 kgf.	
Needle Attachment	For USP 0 size suture, needle attachment must be larger than 1.50 kgf.	

Suture (USP 2, UHMWPE)

Test item	Requirements	Results
Length	The length of suture was measured while the strand is laid out smooth, without tension, on a plane surface: the length of the strand is not less than 95.0 percent of 750mm.	Pass

Tensile Strength	For USP 2 size suture, tensile strength must be larger than 3.52 kgf.	

Suture (USP 0, USP 2, UHMWPE)

Test item	Requirements	Results
Appearance	The test article shall be no damage to the appearance in visual inspection.	Pass
Diameter	For USP 0 size suture, diameter must be within 0.35~0.399mm. For USP 2 size suture, diameter must be within 0.50~0.599mm.	

Suture (USP 0, USP 2, UHMWPE)

Test item	Requirements	Results
Tensile strength	With 25~35cm/min, record the load-displacement curves and maximum load. (N)	Pass

2) Biocompatibility
UHMWPE + PET

#	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
7	Implantation test	ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone	Pass
8	Hemolysis test	ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	Pass
9	Subchronic toxicity	ISO 10993-11 Tests for systemic toxicity	Pass

Only UHMWPE

#	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

7	Implantation test	ISO 10993-6, Tests for local effects after implantation, Annex D test methods for implantation in bone	Pass
8	Hemolysis test	ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	Pass
9	Subchronic toxicity	ISO 10993-11 Tests for systemic toxicity	Pass

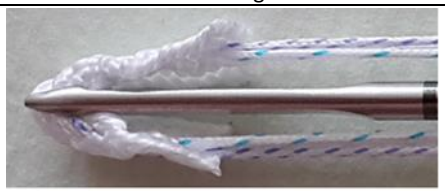
The performance tests demonstrated that Fixone All Suture Anchor performs in a substantially equivalent manner to the predicate device.

Endotoxin Test

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

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

7. Predicate device comparison table

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
510(k) No.	K192709		N/A
Intended Use	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Fixone All Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Fixone All Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.	Identical
Classification name	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Identical
Trade name	Fixone All Suture Anchor	Fixone All Suture Anchor	N/A
Model/type	14 model codes including FAS-1652802ew	61 model codes including FAS-1652802ew	N/A
Appearance			Identical
Product configuration	Driver Suture Anchor	Driver Suture Anchor Needle for JM type	Different
Material	Non-absorbable Suture	Non-absorbable Suture	Identical
Suture			
Absorbable	Non-absorbable	Non-absorbable	Identical
Suture diameter	0.50~0.599 (USP size 2)	0.50~0.599 (USP size 2) 0.30~0.399 (USP size 0)	Different
Material	UHMWPE, PET	UHMWPE, PET	Identical
Sterilization	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	Identical
Biodegradable	Yes	Yes	Identical

Manufacturer	AJU Pharm Co.,Ltd.	AJU Pharm Co.,Ltd.	Remark
Principle of operation	Manual	Manual	Identical
Shelf-life	5 years	5 years	Identical

Difference #1 Product configuration

JM type that include needle are added. This needle intended to penetrate suture to soft tissue.
The needle included in the JM type is identical to the needle included in the K192032 product, and the production process is also the same.

Difference #2 Suture Diameter

USP 0 size suture is added. Thinner suture could cause the early break than thicker suture.
So, we have done the performance test report of USP 0 size suture.

9. Conclusion

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