August 2, 2024

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

Re: K233601
Trade/Device Name: Fixone Meniscal Repair
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 18, 2024
Received: June 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233601

Device Name

Fixone Meniscal Repair

Indications for Use *(Describe)*

The Fixone Meniscal Repair is intended to suture the meniscus tear to facilitate percutaneous or endoscopic soft tissue procedures.

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.

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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 : July 26, 2024
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission type : Traditional

2. Device Information

1) Trade name : Fixone Meniscal Repair
2) Common name : Fastener, Fixation, Nondegradable, Soft tissue
3) Regulation name : Smooth or threaded metallic bone fixation fastener
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

Primary Predicate
K153667, DePuy Synthes/ TRUESPAN Meniscal Repair System (Product Code: MBI)

Additional Predicate
K121861, Smith & Nephew Inc. / FAST-FIX Meniscal Repair System (Product Code: GAT)

Reference Device
K203523, Aju Pharm Co., Ltd / Fixone Hybrid Knotless Anchor (Product Code: MAI)
K230892, Aju Pharm Co., Ltd / Fixone Biocomposite Anchor (Product Code: MAI)

4. Device Description

The Fixone Meniscal Repair are all-inside meniscal repair devices.

Each device includes two peek anchors, pre-tied with non-absorbable suture pre-loaded into a needle delivery system with an adjustable length depth limiter.

The device is made to insert into the joint, place and fix the first anchor(T1) around the ruptured meniscus cartilage, and then place and fix the second anchor(T2) to make one Stitch to seal the torn cartilage.

The device is provided sterile for single use only.

5. Intended Use/Indications for Use

The Fixone Meniscal Repair is intended to suture the meniscus tear to facilitate percutaneous or endoscopic soft tissue procedures.

6. Indications for Use Comparison

The indications for use of the Fixone Meniscal Repair are a subset of the predicate device.

7. Technological Characteristics Comparison

The subject device and predicate device both contain PEEK anchors for meniscal repair. The specific design of the anchors, inserter, and suture are different than the predicate.

8. Performance data:

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 prior related devices. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Biocompatibility of the anchor and suture were leveraged from K203523 and K230892, respectively. Biocompatibility of the other portions of the device were evaluated per ISO 10993-1.

Test item		Requirements	REP NO
Extraction test	Property	When observing it with the naked eye, test solution should be clear and have no foreign particles.	MD2019-00537
	pH	The difference should be 1.5 and less.	
	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.	
	UV spectrum(250 nm~350nm)	Maximum absorbance between 250 to 350 nm should be 0.1 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	
	Extractable color(Suture)	MFDS guideline 2021-3 10.non-absorbable suture	MD2019-00301
EO residual		ISO 10993-7, Ethylene oxide Sterilization residuals	19-061191-02-1 MD2019-00273
Sterility test			
Comparison test	Pull-out	1.Fixone Meniscal Repair 2.FAST-FIX Meniscal Repair System	AJU-MD20230728-01
	Fatigue test		
Shelf life testing 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			AJ-SLR1902(R0)
Comparison test Benchtop performance testing simulating clinical usage			**AJU-MD20240613-01(R1)**

Test item	Requirements
External surface	The test article shall be no damage to the appearance in visual inspection.
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% of 750mm.
Diameter	According to the Technical document (MFDS Notification No.2020-20, “Nonabsorbable Surgical Suture, 4. Diameter”) with <Table 1>
Needle attachment	Under the conditions of “Surgical suture, non-absorbable, with/without needle” in notification No.2020-97 of MFDS, the test articles should meet the test requirements.
Tensile strength (Knot)	Under the conditions of “Surgical suture, non-absorbable, with/without needle” in notification No.2020-97 of MFDS, the test articles should meet the test requirements.
EO residual	ISO 10993-7, Ethylene oxide Sterilization residuals
pH	The difference should be 1.5 and less.
Potassium permanganate	The difference of the consumption of potassium permanganate should

reducing substances	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.

Endotoxin Test

#	Test item	Test method / Test criteria
1	Endotoxin test	USP 42 <85>, Bacterial endotoxin test (LAL)
2	Pyrogen test	USP 42 : 2019, <151> Pyrogen test

Endotoxin test will be conducted for each batch of product before shipment. The test will be carried out using the Limulus Amebocyte Lysate (LAL) method, recognized by the FDA and internationally. Batches that do not pass the Endotoxin Test will be entirely discarded. Discarded lots will be documented separately for management purposes. This document will be part of our produce management and quality assurance procedures.

9. Conclusion

The substantial equivalence of the Fixone Meniscal Repair is based on similarities between the intended use, the specifications, and the non-clinical performance testing of the device compared to the legally marketed predicate device. Therefore, it is concluded that Fixone Meniscal Repair is substantially equivalent to the legally marketed predicate device.