December 15, 2020

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

Re: K192709
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: September 20, 2019
Received: September 27, 2019

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)*
K192709

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.

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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 : Sep. 01, 2019
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Mar.11, 2020

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

K133224, ConMed Corporation / Y-Knot RC All-Suture Anchor w/Two and Three #2

4. Device description

Fixone All suture anchor consists of one “fix Suture” and two or three non-absorbable Sutures. The non-absorbable suture is manufactured from UHMWPE and PET fibers. Fixone All suture anchor is implanted using its self-punching option. 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.

This device is could used with instrument that manufactured by Aju Pharm Co.,Ltd. It is consist of 4 models. It provide non-sterile (user must sterilization before use).

Product name	Instrument / 4 model codes including Fixone.I.B-Awl450a
Model name	Fixone.I.B-Awl450a, Fixone.I.B-Awl550a, Fixone.I.B-Awl450ak, Fixone.I.B-Awl550ak
Intended use	The instrument for making a hole in the bone
Manufacturer	Ajupharm / Korea
Sterilization	Non-sterile
Sterilization method	Autoclave / 132℃ / 4min / 20 min dry

5. 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.

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
Surface	When examined by normal vision, the surface shall be free from defects.		Pass
Nominal size (Exclude suture)	When tested by Vernier calipers, micrometer or tapeline, the measurement should be in accordance with standard.		MD2018-00210
Sterilization	ISO 11135:2014-Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices		ME-SVP-1802
Shelf Life and Packaging	ISO11607-2 / EN 868-5 / ASTM F1980-16 / ASTM F88-15 / ASTM F1929:1998		AJ-SL1702
Comparison test with predicate device	Insertion test	10pcf/40pfc Polyurethane block, self-punching / Implantation angle of 90 (vertical)	AJU_MD20201006_PT(Js, Yknot)
	Pull-out test	10pcf/40pfc Polyurethane block, self-punching / Pull-out angle of 90 (vertical) with MTS Bionix servohydraulic tester	
	Fatigue test	10pcf/40pfc Polyurethane block, self-punching / with same cycle loading and rate	

1-1) Comparison testing process was based on the test of predicate device. See attached 'Biochemical Comparison_All Suture Anchor' / 'Fixation Strength Biochemical Data'.

2) Biocompatibility

#	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.

7. Predicate device comparison table

Manufacturer	ConMed Corporation	AJU Pharm Co.,Ltd.	Remark
510(k) No.	K133224		N/A
Indication 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.	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.	Same
Classification name	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Same
Trade name	Y-Knot RC All-suture Anchor	Fixone All Suture Anchor	N/A
Model/type	-	14 model codes including FAJ-1652802ew	N/A
Appearance			Similar
Product configuration	Driver Suture Anchor	Driver Suture Anchor	Same
Material	Non-absorbable Suture	Non-absorbable Suture	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	Non-absorbable Suture	Non-absorbable Suture	Same
Sterilization	EO Gas sterilization According to ISO 11135: 2014	EO Gas sterilization According to ISO 11135: 2014	Same
Biodegradable	Yes	Yes	Same
Principle of operation	Manual (Self punching)	Manual (Self punching)	Same
Shelf-life	5 years	5 years	Same
Performance testing	Pull-out Insertion Fatigue	Pull-out Insertion Fatigue	Same

8. 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.