January 5, 2021

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

Re: K193497
Trade/Device Name: Fixone Biocomposite Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 1, 2020
Received: December 8, 2020

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)*
K193497

Device Name
Fixone Biocomposite Interference Screw

Indications for Use *(Describe)*
Fixone Biocomposite Interference Screws are indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) 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.

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

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"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 : Dec. 01, 2019
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Nov. 30, 2020
9) Submission type : Traditional
10) Prior related submissions : K192484, B-type anchor

2. Device Information

1) Trade name : Fixone Biocomposite Interference Screw
2) Common name : Screw, Fixation, Bone
3) Regulation name : Smooth or threaded metallic bone fixation fastener
4) Product code : HWC
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

K032224, Smith&nephew, Inc. / Smith & Nephew BIORCI HA Screw

4. Device description

The Fixone Biocomposite Interference Screws are intended to be used for fixation of bone-tendon-bone or soft tissue grafts during anterior or posterior cruciate ligament reconstruction surgery.

This device is could used with instrument that manufactured by Aju Pharm Co.,Ltd. It is consist of 6 models. It provide non-sterile (user must sterilization before use).

Product name	Instrument / 6 model codes including Fixone.I.I-T8090
Intended use	To make a thread and insert a screw in the hole
Manufacturer	AJU Pharm Co.,Ltd. / Korea
Characteristic	This device is provided as Non-sterile and Reusable device. This device is provided non-sterile. This device is user-sterilized.
Sterilization method	Autoclave / 134℃/ 20 min
Material	Grip : Aluminum (Anodized) / Shaft : Stainless Steel (SUS304)
Product code	LXH – Orthopedic manual surgical instrument (Class I)
Pilot Hole	4.5 ~ 5.5 mm

5. Intended Use :

Fixone Biocomposite Interference Screws are indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

6. Performance data:

1) Bench test were performed. Bench testing included biocompatibility, mechanical testing, and 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	ASTM F2502 and USP<28>	Pass MD2014-00216
Measurement	When tested by vernier calipers, the tolerance should be within ±5%	
Tensile strength	The average strength of 10 stands is not less than 100N.	
Extractable color	Weigh a quantity of suture, equivalent to not less than 250mg, and place in a conical flask containing 1.0mL of water for each 10mg of the sample. Close the flaskm and allow it to stand at (37±0.5)℃ for 24 hours. Coll, decant the water from the suture, and compare it with the matching solution : any color present is not more intense than of the appropriate matching solution.	
Insertion torque	Tested with ASTM F2502-Standard specification and test methods for bioabsorbable plates and screws for internal fixation implants	Pass AJU-M20201006-01
Fixation strength (Push-out test)	Tested with ASTM F2502-Standard specification and test methods for bioabsorbable plates and screws for internal fixation implants	
Tested subject and predicate device under same condition for the comparison		
Extraction test		
pH	The difference should be 1.5 and less.	Pass MD2014-00132
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 forign particles.	
Performance Testing of Fixone® Biocomposite Anchor (Pull-out test) Pull-out test by immersion time of saline solution to evaluate two bioabsorbable suture anchors. [Absorption time (soaking time) : 4 weeks, 6 weeks, 12 weeks and 26 weeks ASTM F1839-08, Standard specification for RGID Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments		Ajum20170428-01

2) Biocompatibility

Screw

#	Test item	Test method / Test criteria	Test	Rep No.

			Result	
1	Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices - Part5: Tests for in vitro cytotoxicity	Pass	MD2014-00216
2	Acute systemic toxicity test	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass	MD2014-00132
3	Pyrogen Test	ISO 10993-11 Test for systemic toxicity, pyrogen test	Pass	MD2014-00132
4	Intracutaneous(intradermal) reactivity test	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass	MD2014-00132
5	Maximization test for delayed hypersensicivity	ISO 10993-10 Test for irritation and skin sensitization, Maximization test for delayed hypersensitivity	Pass	MD2014-00216
6	Bacterial revers mutation test	ISO 10993-3 Genotoxicity test OECE 471, Bacterial reverse mutation test	Pass	MD2014-00133
7	Mammalian erythrocyte micronucleus test	ISO 10993-3 Genotoxicity test OECE 471, Bacterial reverse mutation test	Pass	MD2014-00133
8	Implantation test	ISO 10993-6 Tests for local effects after implantation, Annex D test methods for implantation in bone	Pass	MD2014-00104
9	Bioabsorbable screws test	ASTM F2502 Standard specification and test methods for bioabsorbable plates and screws for internal fixation implants	Pass	MD2014-00104
10	Subchronic toxicity test	ISO 10993-11 Biological Evaluation of Medical Devices Part 11-Test for systemic toxicity	Pass	D00021847001-800565.1

The performance tests demonstrated that Fixone Biocomposite Interference Screw performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

The Fixone Biocomposite Interference Screw has the similar device characteristics as the predicated device, the Smith & Nephew BIORCI HA Screw; intended use, material, composition, design and use concept are similar.

The Fixone Biocomposite Interference Screw has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of pertaining to the safety and biocompatibility of Fixone Biocomposite Interference Screw has been conducted.

9. Conclusion

The device is investigated for function to compare the operation of function between Fixone Biocomposite Interference Screw 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 Interference Screw is substantially equivalent to the legally marketed predicate device.