DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 16, 2017

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

Re: K162070
Trade/Device Name: JOINIX Cannular System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 3, 2017
Received: February 8, 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 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 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162070

Device Name
JOINIX CANNULAR SYSTEM

Indications for Use *(Describe)*
For introduction of instrumentation through a portal for surgical procedure.

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 : Jul. 18, 2016
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Jul. 20, 2016

2. Device Information

1) Trade name : JOINIX CANNULAR SYSTEM
2) Common name : Arthroscope
3) Regulation name : Arthroscope
4) Product code : HRX
5) Regulation number : 888.1100
6) Class of device : Class II
7) Panel : Orthopedic

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

K920454, ACUFEX MICROSURGICAL, INC.

4. Device description

This device is intended to puncture the tissue for making the path of surgical instrument in the orthopedic surgery. It is consisted with cannula and trocar. This device is single-use.This device has 3 types. (Threaded type, Smooth type, All smooth type)

5. Intended Use :

For introduction of instrumentation through a portal for surgical procedure.

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.
2) Test standard : ISO 10993 series
3) Test item :
   - Performance test : Appearance, measurement, operation test, leakage
   - Extraction test : Appearance, pH, KM_nO_4 Reducing agents, evaporating residue, heavy metal(as Pb), UV-vis spectrum
   - Biocompatibility test : Cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogen

The performance tests demonstrated that JOINIX Cannular system performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

Manufacturer	AJU Pharm Co.,Ltd.	Acufex Microsurgical Inc.	Remark
510(k) No.	K162070	K920454	N/A
Indication for use	For introduction of instrumentation through a portal for surgical procedure.	For introduction of instrumentation through a portal for surgical procedure.	Same
Classification name	Arthroscope	Arthroscope	Same
Trade name	JOINIX Cannular system	Clear-trac cannula	N/A
Model/type	72 model codes including ACT45045a	N/A	N/A
Appearance			Similar
Product configuration	Cannula Stopcock Trocar	Cannula Stopcock Trocar	Same
Material	Polycarbonate	Copolyester	Different
Inside diameter	4.3mm, 5.3mm, 5.8mm, 6.3mm, 6.8mm, 7.3mm, 7.8mm, 8.1mm	5.0mm 8.0mm	Similar
Length	84mm, 85mm, 111mm, 112mm, 129mm, 130mm,	76mm	Similar
Sterilization	EO Gas sterilization According to ISO 11135: 2007	EO Gas sterilization According to ISO 11135: 2007	Same
Principle of operation	Manual	Manual	Same
Shelf-life	5 years	N/A	N/A

9. Conclusion

The device is investigated for function to compare the operation of function between JOINIX Cannular System 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 JOINIX Cannular System is substantially equivalent to the legally marketed predicate device.