June 20, 2019

Paonan Biotech Co., Ltd.
North Zhong
Regulatory Affairs
3F, No. 50, Lane. 258, Rueiguang Road., Neihu District
Taiwan, R.O.C.
Taipei City, TW 11491

Re: K182285
Trade/Device Name: PK High Tibial Osteotomy Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: KTW, KTT, JDW
Dated: May 13, 2019
Received: May 17, 2019

Dear North Zhong:

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 Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182285

Device Name
PK High Tibial Osteotomy Correction System

Indications for Use *(Describe)*
The PK High Tibial Osteotomy Correction System is an external fixation device, which is intended for use in the treatment of the following indications in the tibia:
- Temporary fracture fixation
- Correction of deformity
- Osteotomy
- Bone union
- Bone reconstruction
- Fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality
- Leg lengthening

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.

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510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92(c).

Submitter Information:	Paonan Biotech. Co., Ltd. 3F, No. 50, Lane. 258, Rueiguang Rd., Neihu District, Taipei City, Taiwan, R.O.C.
Contact Person:	North Zhong TEL: +886-2-2627-4366 FAX: +886-2-2627-4399 Email: northzhong@paonan.com.tw
Date Prepared:	Jun. 19th, 2019
Trade Name:	PK High Tibial Osteotomy Correction System
Common Name:	External Fixator
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Device Class:	Class II
Panel:	Orthopedic
Product Code:	KTW, KTT, JDW
Predicate Devices:	Primary predicate device: TRAUMA-FIX EXTERNAL FIXATOR (K971272) Additional predicates: HOFFMANN 3 MODULAR EXTERNAL FIXATION SYSTEM (K111786, K121252, K122284) ORTHOFIX MODULSYSTEM (K955848)

Device Description:

The PK High Tibial Osteotomy Correction System is a single-use external fixator which consisting of the following components: fixation plate, cortex pin and cancellous pin. Pins are available in various lengths and diameters according to practical requirements. These pins and other components are manufactured from 316L stainless steel (ASTM F138/ ISO 5832-1) and aluminum alloy. These devices are intended to be used in the tibia. Adjustment of the fixator is possible during the course of treatment. All components are provided sterile.

Intended Use:

The PK High Tibial Osteotomy Correction System is an external fixation device, which is intended for use in the treatment of the following indications in the tibia:

- Temporary fracture fixation
- Correction of deformity
- Osteotomy
- Bone union
- Bone reconstruction
- Fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality
- Leg lengthening

Technological Characteristics:

The subjective device narrows the application site from limbs to tibial; thus, the indications in joint arthrodesis and pelvic fixation are not included in the subjective device. Also, the pin size of 2 mm and 3 mm is not included in the subjective device due to those specifications are not intended for use in the lower extremity. The subjective device is made of stainless steel (ASTM F138/ ISO 5832-1) and aluminum alloy, which is the same as the predicate devices. In addition, the subjective device simplified the tradition external fixator; the pin holder clamp, articulation coupling and connecting rod has been incorporate as a fixation plate to improve the manipulation and easy for use. The fixation plate of the subjective device is a base intended to hold cortex and cancellous pins through tightening the respective set screws. The frame type of subjective device is termed unilateral, which is similar to the primary and additional predicates. The rotation angle and displacement between proximal and distal plate can be adjusted through manipulation of universal ring on the fixation plate. Therefore, the subjective device provides same function as the predicate devices.

In summary, the subjective device has the same or similar technological characteristics as the predicate devices.

Non-Clinical Performance Data:

Mechanical testing including static/dynamic axial load test, static torsion test, static cantilever bend test, and four-point bend test were conducted referring to ASTM F1541 to demonstrate substantial equivalence to the predicate system. In addition, grip testing was also performed to demonstrate substantial equivalence to the predicate system. The results demonstrate substantial equivalence of the PK High Tibial Osteotomy Correction System to legally marketed external fixation systems and therefore appropriate for use in the aforementioned indications.

Clinical Performance Data:

Clinical testing was not required for this submission.

Conclusion of Substantial Equivalence:

The PK High Tibial Osteotomy Correction System has been demonstrated to be substantially equivalent to predicate system with respect to intended use, material, technical characteristics and performance. The information provided within this premarket notification supports substantial equivalence of the subjective device to the predicate device.