January 5, 2021

Aike (Shanghai) Medical Instrument Co., Ltd.
Hongying Gu
QC Manager
B320/B321/B322/B323, No. 1128, South Huicheng Road, Jiading Industrial District
Shanghai, 200071
CHINA

Re: K200491
Trade/Device Name: Bfix® Orthopedic External Fixator Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: December 3, 2020
Received: December 9, 2020

Dear Hongying Gu:

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,

Ting Song, Ph.D., R.A.C.
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)*
K200491

Device Name
Bfix® Orthopedic External Fixator Systems

Indications for Use *(Describe)*
The Bfix® Orthopedic External Fixator Systems is intended to be used on adults patients for bone stabilization in the lower limbs.

The indication for use includes:
- open or closed fractures in long bones;
- bone defects or reconstructive procedure
- limb 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.

K200491-510(k) summary

I. Submitter

Aike (Shanghai) Medical Instrument Co., Ltd.
B320，B321，B322, B323，No. 1128, South Huicheng Road，Jiading Industrial District, Shanghai, China

Contact person: Gu Hongying
Position: QC Manager
Phone: +086-13564123520
Fax: +086-021-69522433
E-mail: 314363362@qq.com
Preparation date: 2020-9-08

II. Proposed Device

Trade Name of Device:	Bfix® Orthopedic External Fixator Systems
Common name:	External Fixator Systems
Regulation Number:	21 CFR 888.3030
Regulatory Class:	Class II
Product code:	KTT
Review Panel	Orthopedic

III. Predicate Devices

Predicate device 1
510(k) Number: K113770
Product Code: KTT
Classification: 21 CFR 888.3030
Trade Name: Orthofix Galaxy Fixation System
Common Name: External Fixation Device and Accessories
Manufacturer: Orthofix Srl

IV. Device description

The Bfix® Orthopedic External Fixator Systems is an external fixation system that consists of various components used for the external stabilization of bone fractures. The external fixators components includes ring, connecting rods, thread rods, posts, couplings, telescopic struts, static struts, washer, clamps and pins that combined to construct different frame configuration which is appropriate for each specification

application. The metallic bone pin is implanted into bone and then connected with the external components to form a rigid construct which holds the bone fragments rigidly in place.

V. Indication for use

The Bfix® Orthopedic External Fixator Systems is intended to be used on adults patients for bone stabilization in the lower limbs.

The indication for use includes:

- open or closed fractures in long bones;
- bone defects or reconstructive procedure
- limb lengthening

VI. Comparison of technological characteristics with the predicate devices

The principle of operation for the proposed device and the predicated device is stabilization of bones through fixation with pin clamps to an external fixation frame built with rod. The Bfix® Orthopedic External Fixator System is similar to legally marketed predicated devices in that they are manufactured from similar materials, are of structurally similar size, strength and stiffness, and incorporated similar methods of assembly and adjustable.

VII. Non-Clinical Testing

The mechanical performance of the proposed device has been conduct tests according to ASTM F1541-17 and ASTM F543-17. The following tests were carried out:

- Static bending test,
- Static torsion test,
- Single bending test
- Bending fatigue test
- Axial pull-out test
- Rotational torque test
- Self-tapping performance

VIII. Clinical Testing

It is not applicable.

IX. Conclusion

The proposed device has the same indication for use, has similar design features and technological characteristic as the predicate device. Performance testing data

demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.