April 19, 2024

Beijing KeYi Medical Device Technology Co., Ltd.
Jenny Jiang
Regulatory Affairs Supervisor
Building 1, 30 Yongchang South Road
100176 Beijing, China

Re: K230120
Trade/Device Name: KeYi Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 18, 2024
Received: March 21, 2024

Dear Jenny Jiang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.04.19 01:17:41 -04'00'

For: Lixin Liu, PhD
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)*
K230120

Device Name
KeYi Total Knee System

Indications for Use *(Describe)*

The KeYi Total Knee System indications for use are:

• Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis) or rheumatoid arthritis.
• Correction of functional deformities.
• Post-traumatic loss of knee joint configuration and function.
• Moderate valgus, varus, or flexion deformity.
• Knee fractures untreatable by other methods.

The KeYi Total Knee System is indicated for cemented use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
KeYi Total Knee System

510(k) Owner Information

Name:	Beijing KeYi Medical Device Technology Co., Ltd.
Address:	Building 1, 30 Yongchang South Road, Beijing Economic Technological Development Area, 100176 Beijing, China
Telephone Number:	+86-10-67853877
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Email:	jiangli@keyibangen.com
Contact Person:	Jenny Jiang Regulatory Affairs Supervisor

Date Prepared:	March 18th, 2024

Name of Device

Trade Name / Proprietary Name:	KeYi Total Knee System
Common Name:	Semi-constrained total knee prostheses
Product Code:	JWH
Regulatory Classification:	Class II – 21 CFR § 888.3560 – Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis
Review Panel:	Orthopedic Device Panel
Predicate Devices:	K991581 – NexGen Legacy PS complete knee system
Additional Predicate Device:	K180493 – A3 total knee system
Reason for 510(k) Submission:	New Devices

Device Description

The KeYi Total Knee System is a fixed-bearing, posterior stabilized (PS) arthroplasty device. It is a patellofemorotibial, polymer/metal/polymer, semi-constrained, cemented knee prosthesis that consists of a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral component, ultra-high-molecular-weight polyethylene (UHMWPE) tibial insert, titanium (Ti) alloy tibial baseplate and UHMWPE patellar component. The device has tibial inserts with posts and femoral components with cams that interact with the posts to help stabilize the knee after the posterior cruciate ligament

is removed. The femoral component articulates with the tibial insert component. The underside of the tibial insert component is flat and "snaps" into the tibial baseplate component.

Intended Use / Indications for Use

The KeYi Total Knee System indications for use are:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis) or rheumatoid arthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint configuration and function.
- Moderate valgus, varus, or flexion deformity.
- Knee fractures untreatable by other methods.

The KeYi Total Knee System is indicated for cemented use only.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices

The technological features implemented in the KeYi Total Knee System device are similar to the predicates and no new safety or effectiveness issues are raised. The subject device has the same material technology and is similar in design, function, and application to the predicate devices.

The subject device and both predicate devices are total knee replacement systems consisting of four components: femoral, tibial tray, tibial insert and patella.

The subject device and both predicates have femoral components manufactured from cast cobalt chromium molybdenum (Co-Cr-Mo) alloy. The femoral components of all devices are available in both left and right configurations.

The tibial inserts and patella components of the subject device and both predicate devices are manufactured from conventional ultra-high molecular weight polyethylene (UHMWPE), The range of available sizes of the tibial trays and inserts varies for the subject and predicate devices.

The subject device and primary predicate have a tibial tray manufactured from Ti-6Al-4V. The subject and both predicate tibial trays have a locking mechanism, although the configurations and method of operation are slightly different.

All devices are of a posterior stabilized design and none are cruciate ligament retaining devices. The subject and both predicates are shipped sterile.

The features and characteristics of the subject KeYi Total Knee System device are essentially the same as for the predicate devices with only minor differences that do not raise new questions of safety or efficacy, and all devices have the same intended use.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

The following mechanical tests of the KeYi Total Knee System were performed to support the determination of substantial equivalence:

- FEA Simulation of Tibial Baseplate Fatigue Testing per ASTM F3334
- Tibial Baseplate Fatigue Mechanical Testing per ASTM F1800
- FEA Simulation of Femoral Component per ASTM F3161
- Constraint Testing for Tibia and Femoral Components per ASTM F1223
- Contact Area and Stress Testing for Tibia and Femoral Components
- Constraint Testing for Patella and Femoral Components per ASTM F1223
- Contact Area and Stress Testing for Patella and Femoral Components
- Static Shear and Shear Fatigue Test of Tibial Post
- Tibial Liner Locking Mechanism Test
- Surface Roughness Analysis for Femoral and Tibial Inserts
- Wear Testing per ISO 14243
- Range of Motion Analysis
- Material properties characterization of non-crosslinked UHMWPE
- Pyrogen test of sterile packaged implants

Conclusion

KeYi Total Knee System is substantially equivalent to the predicate devices.