Beijing KeYi Medical Device Technology Co., Ltd. May 14, 2020
Jenny Jiang
Regulatory Affairs Supervisor
Building 1, 30 Yongchang South Road
Beijing, 100176 China

Re: K191826
Trade/Device Name: KeYi Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: April 8, 2020
Received: April 14, 2020

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 (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,

Vesa Vuniqi, MS
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)*

K191826

Device Name
KeYi Total Hip System

Indications for Use *(Describe)*

The KeYi Total Hip System is designed for total hip arthroplasty. The indications for use are:

a. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
b. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
c. Proximal femoral fractures.
d. Avascular necrosis of the femoral head.
e. Non-union of proximal femoral neck fractures.
f. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The KeYi femoral stems are indicated for cementless use. The KeYi acetabular shells are indicated for cemented or cementless use.

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
KeYi Total Hip 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
Fax Number:	+86-10-67853877 ext. 8117
Email:	jiangli@keyibangen.com
Contact Person:	Jenny Jiang Regulatory Affairs Supervisor

Date Prepared:	July 1st , 2019

Name of Device

Trade Name / Proprietary Name:	KeYi Total Hip System
Common Name:	Hip Joint Prosthesis
Product Code:	LPH
Regulatory Classification:	Class II – 21 CFR § 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Review Panel:	Orthopedic Device Panel
Predicate Devices: Additional Predicate Device:	K111472 – HELICON Hip System K980513 – Depuy Articul/Eze femoral Heads K961186 – Depuy Duraloc Cementless Acetabular cup system K001991 – DePuy Titan Porocoat Hip Stem K983491 – Depuy Duraloc Acetabular Cup System-Enduron Liner
Reason for 510(k) Submission:	New Devices

Device Description

The KeYi Total Hip System is a porous-coated, semi-constrained, hip prosthesis designed for either primary or revision hip arthroplasty. The system is comprised of femoral stems and mating metal femoral heads; acetabular shells and mating acetabular liners; optional acetabular cancellous bone screws; and optional acetabular dome hole plug.

The KeYi Femoral Stems are forged titanium alloy, feature a proximal CP Titanium plasma porous coating, and are offered in a range of sizes. The KeYi Femoral Heads are polished

cobalt chromium alloy and designed to mate with 12/14 taper of the femoral stem through taper-locking arrangement and to articulate with the acetabular liner. The heads are available in different sizes with various offsets.

The KeYi Acetabular Shells are manufactured from titanium alloy and feature a porous CP Titanium plasma porous coating. The shells feature a dome hole, are available with a two or three-hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The KeYi Acetabular Liners are manufactured from ultrahigh molecular weight polyethylene (standard/non-crosslinked UHMWPE).

Optional components include threaded acetabular dome hole plugs and acetabular cancellous bone screws, all manufactured from titanium alloy.

Intended Use / Indications for Use

The KeYi Total Hip System is designed for total hip arthroplasty. The indications for use are:

a. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
b. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
c. Proximal femoral fractures.
d. Avascular necrosis of the femoral head.
e. Non-union of proximal femoral neck fractures.
f. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The KeYi femoral stems are indicated for cementless use. The KeYi acetabular shells are indicated for cemented or cementless use.

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

The technological characteristics of the KeYi Total Hip System are similar to predicate devices.

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

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

- Stem fatigue test for KeYi femoral stems per ISO 7206-4
- Neck fatigue test for KeYi femoral stems per ISO 7206-6
- Disassembly test of KeYi acetabular shells and UHMWPE liners per ASTM F1820
- Taper disassembly test of KeYi femoral head and taper per ASTM F2009
- Wear Simulation Test of KeYi acetabular liners per ISO 14242-1
- Range of motion simulation for KeYi total hip system
- Porous coating characterization tests
- Material properties characterization of non-crosslinked UHMWPE
- Biocompatibility test for non-crosslinked UHMWPE per ISO 10993
- Pyrogen test

Conclusion
KeYi Total Hip System is substantially equivalent to the predicate devices.