Beijing AK Medical Co., Ltd.
% Barry Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

June 22, 2018

Re: K180493
Trade/Device Name: A3 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: May 15, 2018
Received: May 21, 2018

Dear Barry Sands:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERV CES
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)

Device Name

A3 Total Knee System

ndications for Use (Describe)

The A3 Total Knee System indications for use is:

- 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 A3 Total Knee System is indicated for cemented use only.

Type of Use (Select one or both as applicable)

[X] 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

Beijing AK Medical Co., Ltd.'s A3 Total Knee System

Submitter Beijing AK Medical Co., Ltd.
Aiguo Liu, FDA Project Team Leader
No. 10 Baifuquan Road
102200, Beijing, China

Contact Person: Barry Sands
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, MA 01913
Phone: 978-358-7307

Date Prepared: February 16, 2018

Name of Device A3 Total Knee System

Name/Address of Sponsor: Beijing AK Medical Co., Ltd.
Aiguo Liu, FDA Project Team Leader
No. 10 Baifuquan Road
102200, Beijing, China

Common or Usual Name

Posteriorly Stabilized Total Knee Replacement

Classification Name

Per 21 CFR as follows:
§888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Product Code JWH
Regulatory Class II

Predicate Devices

Primary - K113550, Biomet Vanguard Complete Knee System
Additional – K031729, Stryker Triatholon Posteriorly Stabilized (PS) Total Knee System

Intended Use / Indications for Use

Intended Use:
The A3 Total Knee System device is a total knee replacement product line. The intended use is the same as the primary predicate device.

Indications for Use:

The A3 Total Knee System indications for use is:

- 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 A3 Total Knee System is indicated for cemented use only.

Technological Characteristics

The technological features implemented in the A3 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 five components:

1. Femoral Condyle
2. Tibial Tray
3. Tibial Insert
4. Patellar Component
5. Locking Mechanism

The subject device and both predicates have femoral condyle and tibial tray 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 of the subject device and primary predicate device are manufactured from conventional ultra-high molecular weight polyethylene (UHMWPE), while the reference predicate is manufactured using a combination of UHMWPE and cobalt-chromium (Co-Cr). 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 patellar component manufactured from UHMWPE, while the material of construct of the patella of the reference predicate is unknown. The subject and both predicate devices have a locking mechanism, although the configurations and method of operation are slightly different. The locking clip for the subject device is manufactured from titanium, the reference predicate locking wire is manufactured from Co-Cr

and the material of the primary predicate is unknown. The subject and primary predicate devices have the same maximum degree of flexion (145°), while the maximum flexion of the reference predicate is slightly less (110°).

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 AK Medical A3 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

The mechanical properties of the AK Medical A3 Total Knee System device were tested in accordance with applicable international standards. The performance testing conducted on the A3 total knee system are listed below.

1. The Tibial Tray Fatigue Testing.
2. The Wear - Mechanical Performance Testing.
3. The Constraint Testing.
4. The Contact Pressure Testing.
5. The Shear Fatigue Testing of the Tibial Post.
6. Surface Roughness Analysis.
7. Physiological Loads Testing on Interlocking Mechanisms.
8. The Shear Fatigue Testing on the Patellar Component.
9. Patella Constraint Testing
10. Patella Contact Testing
11. Static Shear Testing of the Patellar Component

Conclusion

The A3 Total Knee System is substantially equivalent to other legally marketed total knee replacement predicate devices. The A3 Total Knee System has the same general intended use and substantially the same indications for use, technological characteristics, and principles of operation as the previously cleared primary predicate Biomet Vanguard Complete Knee System (K113550) and a second, reference predicate the Stryker Triathlon Posteriorly Stabilized (PS) Total Knee System (K031729). The performance testing – mechanical/bench testing – as well as the same indications for use and materials demonstrate that the A3 Total Knee System is as safe and effective as its predicate devices.