L and K BIOMED Corporation Limited
Semi Jang
RA Deputy Manager
18f, 159-1, Mokdongseo-ro
Yangcheon-gu, Seoul, 07997
Korea

August 3, 2018

Re: K181146
Trade/Device Name: The ASK 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: April 30, 2018
Received: May 1, 2018

Dear Semi Jang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 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)*
K181146

Device Name
The ASK System

Indications for Use *(Describe)*
The ASK System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, avascular necrosis of the femoral condyle, posttraumatic loss of joint configuration. Moderate valgus, varus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. This device may also be indicated in correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure. The ASK System is designed 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.

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a): 1.

Submitter: L&K BIOMED Co., Ltd.
18f, 159-1, Mokdongseo-ro, Yangcheon-gu, Seoul, 07997, Korea
Phone. 82-2-6717-1985
e-mail: smjang@lnkbiomed.com

Contact Person: Semi Jang

Date prepared: March 30, 2018

2. **Device Identification**

Trade Name	The ASK System
Common Name	PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER
Product Code	JWH
Regulatory Class	2
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel/87 as a ClassⅡ device.

3. **Purpose of 510(k)**
The L&K BIOMED Co., Ltd. here by submits this traditional 510(k)

4. **Predicate or legally marketed devices which are substantially equivalent:**
Acculoc Total Knee System (K170753)

5. **Description of the Device**

The ASK System is of the fixed bearing type with a posterior stabilized design and cruciate retained design. It is a patellofemorotibial, polymer/metal/ polymer, semi-constrained, cemented knee prosthesis that consists of a femoral component, tibial insert, tibial tray, and patellar component.
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.

The design and sizing of the femoral components correspond to the natural femoral anatomy, enhancing stress distribution and restoring original femoral dimensions and normal rotation, extension and flexion. Each femoral component has the same intercondylar distance and radius of curvature. Each tibial insert component is complimentarily shaped to conform to the femoral component. The dome shape of each UHMWPE patellar component provides excellent contact with the femoral component and evenly distributes stresses. The dome shape of each patellar component also simplifies implantation by eliminating the need for rotational orientation.

Materials:

Product	Material	Standard
Femoral component	CoCrMo Alloy	ASTM F75
Tibial Tray	Ti-6Al-4V ELI	ASTM F136
Tibial Insert	UHMWPE (GUR 1050)	ASTM F648
Patella	UHMWPE (GUR 1050)	ASTM F648

6. **Indication for Use**

The ASK System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, avascular necrosis of the femoral condyle, posttraumatic loss of joint configuration. Moderate valgus, varus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. This device may also be indicated in correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure. The ASK System is designed for cemented use only.

7. **Comparison of the technological characteristics of the subject and predicate devices**

The ASK System is substantially equivalent to legally marketed device as the Acculoc Total Knee System (K170753). They are similar in design, materials, scientific technologies, intended use, indications and manufacturing process.

8. **Performance Testing**

The ASK System was tested for fatigue performance of the tibial tray, interlock mechanism strength (between the tibial tray and tibial insert), shear fatigue

strength of the tibial insert post, contact pressures and areas, lateral subluxation of patellar component, knee constraint tests, jump distance test and range of motion performance. Test results indicate that the ASK System performs as well as the predicate Acculoc Total Knee System and is capable of withstanding expected in vivo loading without failure. Biocompatibility risk assessment and pyrogenicity testing has also been conducted.

9. **Conclusion**

The ASK System is substantially equivalent to legally marketed predicates.