June 28, 2024

Beijing Chunlizhengda Medical Instruments Co. LTD
% Dave Mcgurl
VP, Orthopedic Regulatory Affairs
Mcra, LLC
803 7th St NW, Floor 3
Washington, District of Columbia 20001

Re: K232175
Trade/Device Name: XN Knee Prosthesis 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

Dear Dave Mcgurl:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on April 14, 2024. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lixin Liu, OHT6: Office of Orthopedic Devices, 301-796-3480, Lixin.Liu@fda.hhs.gov.

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D.
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

June 28, 2024

Beijing Chunlizhengda Medical Instruments Co. LTD
% Dave Mcgurl
VP, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th St NW, Floor 3
Washington, District of Columbia 20001

Re: K232175
Trade/Device Name: XN Knee Prosthesis 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: July 21, 2023
Received: July 21, 2023

Dear Dave Mcgurl:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on April 14, 2024.

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,

Lixin Liu -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232175

Device Name
XN Knee Prosthesis System

Indications for Use *(Describe)*
Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.

Post-traumatic loss of knee joint configuration and function.

Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

Revision of previous unsuccessful uni-knee replacement or other procedure.

The system components are intended 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name: XN Knee Prosthesis System

Manufacturer: Beijing Chunlizhengda Medical Instruments Co. LTD
No. 10 Xinmi West 2nd Road, Southern District of Tongzhou
Economic Development Zone, Tongzho Beijing 101112 China

Contact: Mr. Xie Fengbao
Director, Research and Development
Beijing Chunlizhengda Medical Instruments Co. LTD
No. 10 Xinmi West 2nd Road, Southern District of Tongzhou
Economic Development Zone, Tongzho Beijing 101112 China
Phone: +1 861080561677
xiefengbao@clzd.com

Prepared by: Mr. Dave McGurl
VP, Regulatory Affairs – Orthopedics
MCRA LLC
803 7th Street NW, Floor 3
Washington, DC 20001
Office: 202.552.5797
Cell: 215.275.4786
dmcgurl@mcra.com

Date Prepared: April 12, 2024

Classification: 21 CFR 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Common Name: Total Knee Replacement Prosthesis

Class: II

Product Code: JWH

Primary Predicate: Stryker Triathlon® Total Knee System (K053514)

Reference Devices: Klassic Knee System - Klassic Knee PS-Post Femur; Klassic Knee Tibial Insert, PS-Post, Std Poly; Klassic Knee Tibial Insert, PS-Post, E-Link Poly (K183596)

Klassic Knee System (K112906)

Madison Total Knee System (K192084)

Indications for Use:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful uni-knee replacement or other procedure.

The system components are intended for cemented use only.

Device Description:
The XN Knee Prosthesis System is a knee implant developed by Beijing Chunlizhengda Medical Instruments Co. Ltd. The subject system includes femoral condyle, tibial tray, tibial insert and patella. The fixation method of the system is bone cement fixation. It is mainly used in total knee replacement to repair the diseased or injured knee joint, improve the range of motion of the knee joint and reduce the pain of the patient. The XN Knee Prosthesis System is a Posterior Stabilized (PS) total knee replacement system.

Performance Testing:
Engineering simulation, rationales and testing of the worst-case constructs demonstrates acceptable mechanical performance for the intended use. The complete battery of non-clinical testing, including component interlocking strength, range of motion, wear rationale, and contact area/stress testing, were conducted.

Non-clinical testing and engineering analysis conducted to demonstrate substantial equivalence was as follows:

- Component Interlocking Strength
- Fatigue Under High Flexion
- Tibial Insert Constraint Test
- Surface Roughness Test
- Patella Contact Pressure Test

- Patella Constraint Test
- Static Contact Stress
- Dynamic Fatigue
- Fatigue Performance
- Wear Evaluation
- UHMWPE Characterization

Substantial Equivalence:
The ChunLi XN Knee Prosthesis System is substantially equivalent to the legally marketed predicate, Triathlon® Total Knee System marketed by Stryker Orthopaedics (K053514) with respect to intended use, materials, and fundamental technology.

The subject and predicate systems are both indicated for use in total knee replacement for pathologies, including degenerative joint diseases, post-traumatic loss of configuration and function, deformities and revision procedures. Both systems can be used for posterior stabilized (PS) total knee replacement.

Technological Comparison:
The subject and predicate system designs consist of the same components in left and right configurations in various sizes to accommodate varying patient anatomy, including femoral condyles, tibial trays, tibial inserts, and dome-shaped patella components. The components have similar design features, where the construct replaces and repairs the knee joint and provides a fixed-bearing connection between the tibial component and the PE-insert. The components are provided in a similar size range and the component fixation method is equivalent between the subject and predicate systems: cemented fixation. The subject and predicate are not identical with respect to design, however, both systems are highly similar in that they are cemented fixation, posterior stabilized (PS) for cemented total knee replacement. Both systems include the same component types and materials.

Conclusions:
Testing and engineering analyses showed that the subject components met the pre-determined acceptance criteria identified in the Bench Testing Summary, demonstrating that the subject components are substantially equivalent compared to the predicate components.