



November 21, 2023

TJC Life Co., Ltd
Srinu Krotha
RA Specialist
E1812, Dangsang, SKV1 center, 11
Yeongdeungpo-gu, Seoul 07217
Republic of Korea

Re: K231975

Trade/Device Name: PNK 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: October 31, 2023

Received: November 2, 2023

Dear Srinu Krotha:

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, 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

Enclosure

Indications for Use

510(k) Number (if known)
K231975

Device Name
PNK Total Knee System

Indications for Use (Describe)

The PNK Total Knee 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 PNK Total Knee 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.

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Traditional 510(k)

PNK Total Knee System

510(K) SUMMARY
TJC Life Co., Ltd.
PNK Total Knee System

1. ADMINISTRATIVE INFORMATION

Manufacturer	TJC Life Co., Ltd. E1812, Dangsan, SKV1 Center, 11 Dangsan-ro, 41-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, PIN: 07217 Ph: +82-2-588-1006
Official Contact	SRINU Krotha TJC Life Co., Ltd Email: srk6713@gmail.com
Date Prepared	November 21, 2023

2. ADMINISTRATIVE INFORMATION

Trade/Proprietary Name	PNK Total Knee System
Common Name	Total Knee Joint Replacement Prosthesis
Regulation Number	21CFR 888.3560
Regulation Name	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Class	II
Product Codes	JWH
Review Panel	Orthopedics

3. Purpose of 510(K)

The TJC Life Co., Ltd. Here by submits this traditional 510(K)

4. INDICATIONS

The PNK Total Knee 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 PNK Total Knee System is designed for cemented use only.

5. DEVICE DESCRIPTION

The PNK Total Knee System is of the fixed bearing type with a posterior stabilized design (PS) and cruciate retained design (CR) configurations. It is a Patellofemorotibial, polymer/metal/polymer, semi-constrained, cemented knee prosthesis that consists of a femoral component, tibial tray component, tibial insert component, and patellar component.

The PS version 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 CR version has tibial inserts and femoral components without posts or cams, allowing the posterior cruciate ligament to be “retained” and provide stability to the knee joint.

Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. Total Knee Femoral Component is available in right and left configurations, and eight proportional sizes (sizes 1-8) to accommodate differences in patient anatomy.

Traditional 510(k)**PNK Total Knee System**

The tibial Tray components (tibial baseplate) are made from Ti-6Al-4V titanium alloy, and tibial trays are available in 8 sizes (A-H,) to allow optimal cortical bone coverage of the prepared tibia. The unique stem Diameter for the all 8 sizes.

Tibial Insert components are made from Highly Cross-linked UHMWPE (HXLPE) and are available in 12 proportional sizes that match to corresponding 2 tibial tray components and two femoral components.

Patellar components are made from Highly Cross-linked UHMWPE (HXLPE). The articulating surface of the patellar component is axisymmetric (round) with a flattened sombrero shape and the patella components are available in 6 diameters.

All implant components are provided sterile.

6. PREDICATE DEVICE

Device	Manufacturer	Trade/Model Name	510(K)
Primary Predicate	RootLoc Co., Ltd	Acculoc Total Knee System	K170753
Secondary Predicate	Corentec Co., Ltd	EAUM Total Knee System	K110404
		LOSAPA Total Knee Replacement System	K130673
	OTIS Biotech Co., Ltd	PROLIXUS Total knee System	K170534
	The Progressive Orthopedic Company, LLC	Progressive Orthopedic Total Knee System	K142649

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

The PNK Total Knee System is substantially equivalent in indications for use with the predicate devices. The subject device overall shape, design & material used are similar to the predicate devices. The subject device and the predicate devices encompass a similar range of physical dimensions, including the “Anterior-Posterior” and “Medial-Lateral” dimensions of the femoral and tibial tray components, the thickness of the tibial insert components and the diameter of the patella components. There are no substantial differences in technological characteristics between the two devices and as such the PNK Total Knee system introduces no different issues of safety or effectiveness.

8. NONCLINICAL TESTING

All necessary testing has been performed for the worst-case PNK Total Knee system components to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Clinical data were not needed to support the safety and effectiveness of the subject device.

The device performance was characterized through the following tests, tibial tray fatigue testing, constraint test, contact analysis, Insert disassembly test, tibial insert post shear test, and dislocation/jump distance and range of motion. Cross-linked UHMWPE testing was done as per ASTM F648 and ASTM F2565 requirements. Gamma Sterilization Validation as per ISO 11137 & Ethylene Oxide Sterilization Validation per ISO 11135 and residuals testing as per ISO 10993-7 & ISO 10993-10 were done. Bacterial Endotoxin Testing (BET) conducted as specified in ANSI/AAMI ST72:2011 and Biocompatibility testing has been done as per ISO 10993-1.

9. CONCLUSION

The PNK Total Knee System is substantially equivalent to the predicate device with respect to its indications for use, design, function, and method of fixation.