December 20, 2024

United Orthopedic Corporation
Lois Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 30075
Taiwan

Re: K243024
Trade/Device Name: Cellbrick Knee Spacer
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: September 13, 2024
Received: September 27, 2024

Dear Lois Ho:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.12.20 16:14:33 -05'00'

Jesse Muir, PhD
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*
K243024

Device Name
Cellbrick Knee Spacer

Indications for Use *(Describe)*
This product is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.
This product is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). During the implantation period, patients have to use traditional mobility assist devices (e.g. crutches, walkers, canes) for daily activities.
With pre-clinical validations of antibiotic elution, tibial spacer fatigue test, and knee spacer wear test, only Palacos MV+G bone cement may be used for preparing the spacers.

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.

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510(K) SUMMARY

Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Contact Details

Applicant Name	United Orthopedic Corporation
Applicant Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
Applicant Contact Telephone	+88635773351
Applicant Contact	Mrs. Lois Ho
Applicant Contact Email	lois.ho@unitedorthopedic.com

Device Name

Device Trade Name	Cellbrick Knee Spacer
Common Name	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3560
Product Codes	JWH

Predicate Device Information

510(k) Number	Predicate Trade Name	Product Code
Primary Predicate		
K222570	COPAL® knee moulds	JWH
Predicate or Reference Devices		
K101356	Spacer-K	JWH
K181732	Spacer-K	JWH
K183017	REMEDY® Stemmed Knee Spacer	JWH
K140073	U2 Total Knee System	JWH
K132752	U2 Total Knee System	JWH
K150829	U2 Total Knee System	JWH
K222700	U2 Total Knee System	JWH

Device Description Summary	Cellbrick Knee Spacer is a temporary knee spacer product, it's suitable for the patients with mature skeleton and required to perform two-stage knee joint prosthesis procedure for infection control. It consists of three components, which are (1) Femoral Spacer, (2) Tibilal Spacer, and (3) Canal Rod. The Femoral Spacers and the Tibial Spacers are designed with multiaperture features, which can act as carrier of antibiotic-loaded bone

	cement to release antibiotic at infection site. The Canal Rod is optional. - Femoral Spacer The Femoral Spacer is made of UHMWPE (ASTM F648/ISO5834-2). The geometrical appearance of Femoral Spacer is designed and modified based on the 510(k) cleared cruciate-retaining femoral component (K140073). Their articular surface geometry and curvature is identical. In addition, the Femoral Spacer is designed with multiaperture feature. Such scaffold-like features can use as a carrier of antibiotic-loaded cement to release antibiotic at the infection site for infection control. The Femoral Spacer can be used for both of left and right knee because of the symmetric condyle design. Five femoral spacer sizes have been prepared for different anatomical demands with anteroposterior (AP) and mediolateral (ML) dimensions. The Femoral Spacer is designed “same/ one up” sizing options with the tibial spacers. - Tibial Spacer The Tibial Spacer is made of UHMWPE (ASTM F648/ISO5834-2). The bearing surface’s curvature and geometrical design of the tibial spacer is the same as the 510(k) cleared ultra-congruent tibial insert (K132752, K150829, and K222700). The Tibial Spacer is designed with multiaperture feature as well. This scaffold-like feature is used as a carrier of antibiotic-loaded cement to release antibiotic at the infection site for infection control. Five Tibial Spacer sizes have been prepared for different anatomical demands with anteroposterior (AP) and mediolateral (ML) dimensions. - Canal Rod The canal rod is made of Ti-6Al-4V alloy (ASTM F136/ISO 5832-3). As a carrier, the rod provides the area for cement to attach so that to increase the surface area of cement. The canal rod is an optional device, it could be applied to patient with deeper infection problem, applying Canal Rod can make surgeon placing antibiotic-loaded cement into the deeper infection site. The Canal Rod is provided with one dimension: Ø 4(diameter) ×80mm (length).
Intended Use/ Indications for Use	This product is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

	This product is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). During the implantation period, patients have to use traditional mobility assist devices (e.g. crutches, walkers, canes) for daily activities. With pre-clinical validations of antibiotic elution, tibial spacer fatigue test, and knee spacer wear test, only Palacos MV+G bone cement may be used for preparing the spacers.
Indications for Use Comparison	The indication for use of the subject device is substantially equivalent to the primary predicate. Although the content of indication for use is not completely identical, however, both of the subject device and primary predicate are temporary implants (maximum of 180 days), which is intended to apply for the patient with mature skeleton and required a two-stage procedure due to a septic process. In addition, both should use mobility assist devices during the period of implantation. Base on above mentioned, the indication for use of subject device is considered as substantially equivalent to the primary predicate.
Technological Comparison	The technological characteristics of the subject device are substantially equivalent to those of the primary predicate (K222570), as the comparison given below shows. - Their intended use is the same. - The intended users, intended surgical procedure, body contact and duration, and fixation method are identical to the primary predicate. - For the difference in the material, appearance design, specification, device X-ray visibility, and sterilization method, evaluation and verification activities were conducted, and the equivalent safety and effectiveness compared to the predicate devices were validated. It established that no new risks arise compared to those of the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions	Based on the technological characteristics of the subject device, the following evaluation and tests were conducted to validate the safety and effectiveness of the subject device. - Fatigue test for Tibial spacer - Range of Motion - Constraint performance on the tibiofemoral interface - Wear test - Antibiotic release test & In vitro antibiotic test - Usability evaluation - Endotoxin testing Not Applicable. Based upon equivalences in intended use, patient population, site of application, conditions of use, and non-clinical performance data, the Subject device has been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.