



March 25, 2026

Curexo, Inc.
Jay Koh
Regulatory Affairs Manager
3rd 4th FL. 480, Wiryehunhwan-ro, Songpa-gu
Seoul, 05814
Republic Of Korea

Re: K252037
Trade/Device Name: CUVIS-joint (CJ150)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 22, 2026
Received: February 23, 2026

Dear Jay Koh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

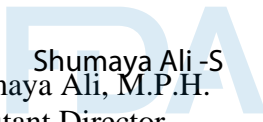
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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,


Shumaya Ali-S
Shumaya Ali, M.P.H.
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

Indications for Use

Submission Number (if known)

K252037

Device Name

CUVIS-joint (CJ150)

Indications for Use (Describe)

Indications for Use

The CUVIS-joint is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The CUVIS-joint is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The CUVIS-joint is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The CUVIS-joint facilitates accurate positioning of TKA implants, relative to these alignment axes.

The CUVIS-joint is compatible with the following Knee Implant System:

-United U2 Knee System

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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**510(k) SUMMARY
K252037**

Applicant Information:

Owner Name: CUREXO, Inc.
Address: 3rd, 4th, 480 Wiryehwan-ro, Songpa-gu,
Seoul, 05814, Republic of Korea
Phone number: +82-2-6202-8500
Fax number: +82-2-3446-4498
Establishment Registration Number: 3009522766
Contact Person: Jay Koh
Date Prepared: June 30, 2025

Device Information:

Device Classification: Class II
Trade Name: CUVIS-joint
Common name: Orthopedic Stereotaxic Instrument
Classification name: Stereotaxic Instrument
Regulation number: 882.4560
Product Code: OLO

Predicate Device:

The CUVIS-joint is substantially equivalent in intended use, materials, fundamental scientific technology and performance to the following legally marketed device in commercial distribution: THINK Surgical, Inc's TSolution One Total Knee Application cleared via K203040 and cleared via K191369.

Device Description:

The CUVIS-joint is a three-dimensional, graphical, preoperative planner and implementation tool for treatment of patients who require total joint arthroplasty. The device is intended as an alternative to manual template planning and preparation of the bone with patients requiring primary total knee arthroplasty (TKA).

The CUVIS-joint consists of two main components: 1) the Planner which is a three-dimensional (3D) preoperative planning workstation which uses preoperative CT scans of patient anatomy to

aid a surgeon in planning the position and orientation of the implant components relative to 3D models of the patient's anatomy, and 2) the Robotic Arm Tool which executes the surgical plan and includes a an electromechanical arm, an arm base including control electronics and computer, optical tracking system, a display monitor, operating software, pendant control, and tools and accessories. When used according to the Instructions for Use (IFU), the CUVIS-joint enables precise implant positioning possible before and during TKA surgical procedures.

Intended Use / Indications for Use:

The CUVIS-joint is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The CUVIS-joint is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The CUVIS-joint is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The CUVIS-joint facilitates accurate positioning of TKA implants, relative to these alignment axes.

The CUVIS-joint is compatible with the following Knee Implant Systems:

-United U2 Knee System

Substantial Equivalence:

Both the CUVIS-joint, and the predicate device, the TSolution One Total Knee Application, have the same intended use. Both are intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The Indications for Use of the CUVIS-joint and its predicate are identical, with the exception of the total joint implant systems with which each is compatible.

There are no significant differences in the patient contacting materials between the CUVIS-joint and the predicate, TSolution One Total Knee Application cleared via K203040. Both use materials that have had a long history of use in orthopaedic medical devices.

Both the CUVIS-joint and the predicate device have operating principles and technological characteristics which are substantially equivalent. Both devices use CT images of the patient's anatomic structure and both use a three-dimensional (3D) preoperative planning workstation that aids a surgeon in planning the position and orientation of the implant components relative to 3D models of the patient's anatomy. Both devices use pinless point to surface registration of the femur and tibia by collecting landmarks on the bone surface to digitize the location of each bone.

Both devices use bone markers for intraoperative tracking of the position of the bones relative to the electromechanical arm and to recover from bone motion that may occur during the surgery. The CUVIS-joint uses tracking arrays that are optically tracked relative to the robot base, while the TSolution One Total Knee Application uses a mechanical motion detection arm attached from the robot base to each bone. Both use standard surgical exposures appropriate to the specific anatomic location and consistent with the exposures used in traditional manual surgical procedures.

Both devices have a display monitor, operating software, pendant control, and procedure specific tools and accessories for the implementation of the preoperative plan. Both devices use an electromechanical arm, an arm base including control electronics and computer which mills the bone to achieve the bone preparation required to accept the TKA implants. The CUVIS-joint allows the surgeon to make both pre-operative and intraoperative plan adjustments to the translation, rotation and size of the TKA components to support gap balancing.

Performance testing was performed on the CUVIS-joint to verify and validate that the performance of the system meets the user needs and that the device is substantially equivalent to the predicate. This testing included: Biocompatibility Testing, Full System Run Through Testing (Smoke Test), Cutting Accuracy Testing, Cadaver Validation Testing, Electrical Safety and EMC Testing, Software Testing and Usability Testing.

Substantial equivalence in technological characteristics and performance of the CUVIS-joint compared to the predicate device is outlined in the table below:

Product	CUVIS-joint	TSolution One Total Knee Application (Predicate Device)	TSolution One Total Knee Application (Predicate Device)	Conclusion
510(k) number	Subject Device	K203040	K191369	
Manufacturer	CUREXO, Inc.	THINK Surgical Inc	THINK Surgical Inc	
Materials				
-Material Used	Uses materials with a long history of use in orthopedic procedures.	Uses materials with a long history of use in orthopedic procedures.	Uses materials with a long history of use in orthopedic procedures.	SAME.
Technological Characteristics				
-Patient Imaging	CT Scan	CT Scan	CT Scan	SAME
-User Controls	Keyboard, mouse, Pendant with mechanically latched Stop Button, foot switch	Keyboard, mouse, Pendant with mechanically latched Stop Button	Keyboard, mouse, Pendant with mechanically latched Stop Button	Substantially Equivalent (Both systems have similar user controls – CUVIS-joint adds an optional foot switch for use in collecting registration points)
-Preoperative planning workstation	Three-dimensional preoperative planning workstation	Three-dimensional preoperative planning workstation	Three-dimensional preoperative planning workstation	SAME
-Presurgical Plan	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop implant size and location	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop implant size and location	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop implant size and location	SAME
-Surgical Plan Data	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm. System allows pre-operative and intraoperative plan adjustment to the translation, rotation and size of the TKA components to support gap balancing.	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm. System allows only pre-operative plan adjustment to the translation, rotation and size of the TKA components to support gap balancing.	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm. System allows only pre-operative plan adjustment to the translation, rotation and size of the TKA components to support gap balancing.	Substantially Equivalent (Both systems use a high level preoperative plan to control the robotic arm – CUVIS-joint allows for intraoperative plan adjustments)

Product	CUVIS-joint	TSolution One Total Knee Application (Predicate Device)	TSolution One Total Knee Application (Predicate Device)	Conclusion
510(k) number	Subject Device	K203040	K191369	
-Surgical Exposure	Similar to traditional surgical exposure for the anatomic site	Similar to traditional surgical exposure for the anatomic site	Similar to traditional surgical exposure for the anatomic site	SAME
-Preparation of bones to accept TKA implants	-Electromechanical arm mills the bone to implement pre-surgical plan	-Electromechanical arm mills the bone to implement pre-surgical plan	-Electromechanical arm mills the bone to implement pre-surgical plan	SAME
-Intraoperative tracking of the position of the bones relative to the electromechanical arm	Uses an optical tracking array to track the position of the bones relative to the electromechanical arm	Uses a mechanical motion detection arm to track the position of the bones relative to the electromechanical arm	Uses a mechanical motion detection arm to track the position of the bones relative to the electromechanical arm	Substantially Equivalent (Both systems use an intraoperative tracking system – CUVIS-joint uses optical tracking while TS1 uses a mechanical motion arm)
-Patient/Robot Registration	Pinless point to surface registration of the femur and tibia by collecting landmarks on the bone surface matched to the 3D bone model created from the CT scan	Pinless point to surface registration of the femur and tibia by collecting landmarks on the bone surface matched to the 3D bone model created from the CT scan	Pinless point to surface registration of the femur and tibia by collecting landmarks on the bone surface matched to the 3D bone model created from the CT scan	SAME
-Use of Markers Attached to the Bone for Motion Recovery	Uses Tracking Arrays attached to the bone which are optically tracked to detect motion.	Uses Bone Motion Recovery Markers attached to the bone which are tracked using the digitizing arm.	Uses Bone Motion Recovery Markers attached to the bone which are tracked using the digitizing arm.	Substantially Equivalent (Both systems use bone markers for motion recovery – CUVIS-joint tracks them optically while TS1 tracks them with the digitizer arm)
-System is Compatible with specified Knee Implant Systems	Verification and Validation Testing of Individual Implant Systems is Provided to Support the use of specified Knee Implant Systems	Verification and Validation Testing of Individual Implant Systems is Provided to Support the use of specified Knee Implant Systems	Verification and Validation Testing of Individual Implant Systems is Provided to Support the use of specified Knee Implant Systems	SAME
Performance Testing				
-Full System Run Through Testing (Smoke Test)	Passed	Passed	Passed	SAME

Product	CUVIS-joint	TSolution One Total Knee Application (Predicate Device)	TSolution One Total Knee Application (Predicate Device)	Conclusion
510(k) number	Subject Device	K203040	K191369	
-Cutting Accuracy Verification	Passed	Passed	Passed	SAME
-Cadaver Lab Validation Testing	Passed	Passed	Passed	SAME
-Software Testing	Passed	Passed	Passed	SAME
-Electromagnetic Compatibility and Electrical Safety	Passed	Passed	Passed	SAME
-Biocompatibility Testing ISO 10993-1:2018	Passed	Passed	Passed	SAME
-Usability Testing	Passed	Passed	Passed	SAME

Clinical Data:

Following PRISMA guidelines, a structured literature search was conducted in September 2025 to identify studies reporting key clinical performance and safety endpoints related to CUVIS-joint and its equivalent device, TSolution One. The review included data on implant positioning, mechanical axis correction, functional recovery, and adverse event profiles, with particular attention to adverse events rates and device-related complications. The collected evidence was analyzed to determine whether the devices meet established clinical safety criteria and demonstrate acceptable performance in orthopedic surgical practice.

The search identified 1,571 papers. These papers were evaluated sequentially based on predefined exclusion criteria. Studies were excluded if they were not relevant to the total knee arthroplasty (TKA) or if they did not meet methodological or clinical relevance standards. Only publications meeting the predefined criteria for study design, relevance, and contribution to the evaluation of clinical safety and performance were included in the final analysis.

Of the 22 clinical studies on the performance of CUVIS-joint and its equivalent device, a meta-analysis was conducted on 4 studies that reported the mean Hip-Knee-Ankle (HKA) angle as a quantitative surgical outcome. The combined analysis of 656 patients yielded a mean HKA angle within the clinically acceptable range of $\pm 3^\circ$, which met the acceptance criteria of the analysis and suggested that the CUVIS-joint system achieves clinically acceptable alignment accuracy. Further analysis of selected studies demonstrated that both systems contributed to accurate implant positioning and limb alignment, improved postoperative patient reported outcomes (including: KSS, WOMAC, OKS, AKSS, FJS and SF-12), and consistent surgical outcomes.

These findings support equivalent clinical efficacy of robotic-assisted TKA using CUVIS-joint to other comparable technologies and to those commonly reported for conventional total knee arthroplasty (TKA) procedures.

In terms of safety, the overall adverse event rate across the reviewed studies remained below 1%, with device-related adverse events being rare and typically resolved without further complications. Therefore, both CUVIS-joint and TSolution One can be considered comparable in terms of clinical safety and similar to results reported for conventional TKA procedures. Taken together, the evidence from more than 2,000 clinical cases reported in this systematic review supports the use of the CUVIS-joint system and its predicate device as equivalently safe and effective options for robotic-assisted TKA. The CUVIS-joint system demonstrates clinically meaningful benefits in both performance and safety in total knee arthroplasty (TKA).

Conclusion

The CUVIS-joint is equivalent to the predicate, TSolution One Total Knee Application, cleared via K203040 in the following ways: it has the same intended use and Indications for Use and substantially equivalent technological characteristics and operating principles and incorporates the same basic design and similar materials. The results of performance testing demonstrate that the CUVIS-joint performed substantially equivalent to the predicate and did not raise any new questions of safety and effectiveness. Clinical data from the published literature further supports equivalent safety and effectiveness of the CUVIS-joint and demonstrated a positive risk/benefit for the indication for total knee arthroplasty. The data presented supports a determination of Substantial Equivalence.