June 22, 2023

Sujin Yang
RA Staff
577, Gangnam-Daero, Seocho-Gu
Seoul, 06530
Korea, South

Re: K223558
Trade/Device Name: CUVIS-spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 23, 2023
Received: November 28, 2022

Dear Sujin Yang:

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/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 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 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, MPH
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)*
K223558

Device Name
CUVIS-spine

Indications for Use *(Describe)*
CUVIS-spine is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of guide bush to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous pedicle screw placement provided that the required markers and rigid patient anatomy can be identified on 3D or 2D image.

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."

5. 510(k) Summary

5.1. General Information

Applicant/Submitter:	CUREXO, INC.
Address:	577, Gangnam-Daero, Seocho-Gu Seoul, 06530, Republic of Korea Tel: +82-31-788-7938 Jungeun PARK Quality Management Representative Email: jepark@curexo.com
Contact Person:	Su Jin Yang
Address:	4-5, Yanghyeon-ro 405beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea Tel: +82-31-788-7938 Email: sjyang@curexo.com
Preparation Date:	November 25, 2022

5.2. Device Name and Code

Device Trade Name:	CUVIS-spine
Model Name:	CS200
Common Name:	Pedicle Screw Guide System
Classification Name:	Orthopedic Stereotaxic instrument
Product Code:	OLO
Regulation Number:	21 CFR 882.4560
Classification:	II
Review Panel:	Orthopedic

5.3. Predicate Device

CUVIS-spine is substantially equivalent to the following legally marketed predicate devices

Table 1 Primary Predicate device

Applicant	Device Name	510(k) Number
CUREXO, INC	CUVIS-spine	K201569

Table 2 Other predicate device

Applicant	Device Name	510(k) Number
Globus Medical Inc.	Excelsius GPS™	K171651

5.4. Device Description

The CUVIS-spine is a mobile system mainly comprising the robotic arm, the main console and the staff console as an option. The robotic arm is positioned on the floor near the side of the surgical table. The location of the main console or the staff console is appropriately determined considering the user preference and the environments.

CUVIS-spine is a pedicle screw guide system which consists of Robotic Arm, Main Console, Staff Console, Guide bush, Source Calibrator, Registration Tool, Registration Tool Adapter, Drape, Marker Ball, Patient Marker, Clamp, Adapter, Pin, Pin vise, Slide Hammer, Marker Driver, Detector calibrator, Dilator, Serration-tip dilator, Bur, Awl, Probe, Lenke probe, Tapper, Stylet tapper, Screwdriver, Instrument container.

5.5. Indications / Intended Use

CUVIS-spine is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of guide bush to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous pedicle screw placement provided that the required markers and rigid patient anatomy can be identified on 3D or 2D image.

5.6.Technical Characteristics in Comparison to Predicate Devices

CUVIS-spine is substantially equivalent to the following legally marketed predicate devices

Table 3 Technical Characteristics in Comparison to Predicate Devices

	Subject Device	**Primary predicate Device**	**Other predicate Device**
Device	**CUVIS-spine**	**CUVIS-spine (K201569)**	**Excelsius GPS™ (K171651)**
Device Description and indications for use			
Manufacturer	CUREXO, INC.	CUREXO, INC.	Globus Medical Inc.
Classification	Class II	Class II	Class II
Product Code	OLO	OLO	OLO
Regulation No.	882.4560	882.4560	882.4560
General Device description	The CUVIS-spine is a mobile system mainly comprising the robotic arm, the main console and the staff console as an option. The robotic arm is positioned on the floor near the side of the surgical table. The location of the main console or the staff console is appropriately determined considering the user preference and the environments.	The CUVIS-spine is a mobile system mainly comprising the robotic arm, the main console and the staff console as an option. The robotic arm is positioned on the floor near the side of the surgical table. The location of the main console or the staff console is appropriately determined considering the user preference and the environments.	The EXCELSIUS GPS™ is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images(preoperative CT, intraoperative CT and luoroscopy), using a dynamic reference base and positioning camera.
Indications for use	CUVIS-spine is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of guide bush to be used by surgeons for navigating and/or guiding compatible	CUVIS-spine is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of guide bush to be used by surgeons for navigating and/or guiding compatible	The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by

	Subject Device	Primary predicate Device	Other predicate Device
Device	**CUVIS-spine**	**CUVIS-spine (K201569)**	**Excelsius GPS™ (K171651)**
	surgical instruments in open or percutaneous pedicle screw placement provided that the required markers and rigid patient anatomy can be identified on 3D or 2D image.	surgical instruments in open or percutaneous surgical procedures if the required markers and rigid patient anatomy can be identified on O-arm or C-arm.	surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopaedic bone screws.
Technical Characteristics			
Principle of operation	-Preoperative images -Intraoperative images -Patient registration -Surgical planning Real-time tracking of navigated instruments -Guidance of instruments	-Intraoperative images -Patient registration -Surgical planning -Real-time tracking of navigated instruments -Guidance of instruments	-Intraoperative/ preoperative images -Patient registration -Surgical planning -Real-time tracking of navigated instruments -Guidance of instruments
Image	O-arm, C-arm, CT	O-arm, C-arm	O-arm, C-arm, CT
Input Images	-3D pre-operative exam -3D intra-operative exam -2D intra-operative exam	-3D intra-operative exam -2D intra-operative exam	-3D pre-operative exam -3D intra-operative exam -2D intra-operative exam
Tracker	Optical Tracking System	Optical Tracking System	Optical Tracking System
Guide	Dilator and Tapper	Dilator and Tapper	Dilator and Tapper
Target Tracking	YES	YES	YES
Integrated Planning	- SRC (Control Software)	- SRC (Control Software)	Excelsius GPS Planning and Navigation

	Subject Device	Primary predicate Device	Other predicate Device
Device	**CUVIS-spine**	**CUVIS-spine (K201569)**	**Excelsius GPS™ (K171651)**
Software	- SPNe (Planner Software)	- SPN (Planner Software)	Application Software
Save/load Planning	YES	YES	YES
Merge images functionality	YES	YES	YES
Trajectory planning parameters	- Entry point - Target point - Instrument length/diameter	- Entry point - Target point - Instrument length/diameter	- Entry point - Target point - Instrument length/diameter
Localization means	Optical system (infrared camera)	Optical system (infrared camera)	Optical system (infrared camera)
Image-guided	YES	YES	YES
Controller	Forced-controlled movement allowing robot arm positioning (called hand guide function)	Forced-controlled movement allowing robot arm positioning (called hand guide function)	Force-controlled movement allowing robotic arm positioning
Patient registration method	- Pre-op CT : Fluoroscopic to pre-op CT merge - Intra-op CT : Registration tool - Fluoroscopy : Source calibrator	- Intra-op CT : Registration tool - Fluoroscopy : Source calibrator	- Pre-op CT : Fluoroscopic to pre-op CT merge - Intra-op CT : Registration fixture - Fluoroscopy : Registration fixture
Real time display of instrument position	YES	YES	YES
Accessories	- Registration instruments (Guide bush, Source calibrator, Registration tool, Registration tool adapter, Detector calibrator)	- Registration instruments (Guide bush, Source calibrator, Registration tool, Registration tool adapter, Detector calibrator)	- Registration instruments

	Subject Device	Primary predicate Device	Other predicate Device
Device	**CUVIS-spine**	**CUVIS-spine (K201569)**	**Excelsius GPS™ (K171651)**
	- Patient reference instruments (Patient marker, Clamp, Pin, Marker ball, Adapter, Pin Vise, Slide Hammer, Probe, Awl, Lenke probe) - Surgical instruments (Marker Driver, Dilator, Serration-tip dilator, Bur, Stylet tapper, Tapper, Screwdriver, Robotic arm drape, Tool drape, Detector drape, Instrument Container)	- Patient reference instruments (Patient marker, Clamp, Marker ball) - Surgical instruments (Marker Driver, Dilator, Serration-tip dilator, Bur, Stylet tapper, Tapper, Screwdriver, Robotic arm drape, Tool drape, Detector drape, Instrument Container)	- Patient reference instruments - Surgical instruments - End effector
Cybersecurity	Industry standard protocols - User access control(admin) - Network protocols and Firewall control - Data cryptography (binary, registry, CSP) - Core resource files are regenerated as new type of files - Event logging - - software update(only admin)	Industry standard protocols - User access control(admin) - Network protocols and Firewall control - Data cryptography (binary, registry) - Core resource files are regenerated as new type of files - Event logging - software update(only admin)	N/A
Performance data			

	Subject Device	Primary predicate Device	Other predicate Device
Device	**CUVIS-spine**	**CUVIS-spine (K201569)**	**Excelsius GPS™ (K171651)**
Electrical Safety and Electromagnetic compatibility	- IEC60601-1 - IEC60601-1-2	- IEC60601-1 - IEC60601-1-2	- IEC60601-1 - IEC60601-1-2
Accuracy verification on anatomical landmarks	Yes	Yes	Yes
Bio-compatibility	The biocompatibility evaluation for the patient marker has been conducted in accordance with EN ISO 10993 standards.	The biocompatibility evaluation for the patient marker has been conducted in accordance with EN ISO 10993 standards.	The biocompatibility evaluation for EXCELSIUS GPS™ has been conducted in accordance with ISO 10993 standards.
Parts of Contact with Patient	Patient marker (Clamp type, Pin type)	Patient marker	Patient reference instruments (Patient marker)
Nature of Body Contact	Implant device / bone	Implant device / bone	Implant device / bone
Patient Fixation	Reference is fixed to patient's body structure for tracking system	Reference is fixed to patient's body structure for tracking system	Reference is fixed to patient's body structure for tracking system

5.7. Performance Data

Non-clinical tests: Pose accuracy and Repeatability of the CUVIS-spine were tested and validated. A cadaveric study of the proposed device had been performed for the robotic-assisted pedicle screw placement.

Biocompatibility were tested using following consensus standards:

- Tests for in vitro cytotoxicity were tested and evaluated according to the FDA-recognized consensus standard, ISO 10993-5.
- Tests for irritation, skin sensitization and intracutaneous reactivity were tested and

evaluated according to the FDA-recognized consensus standard, ISO 10993-10.

Electromagnetic compatibility and electrical safety, etc, were tested using following consensus standards:

- Basic safety and essential performance of the CUVIS-spine is tested and evaluated according to the FDA-recognized consensus standard, ES 60601-1.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented by referring to IEC 60601-1-6.

Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a “MAJOR” level of concern. Cybersecurity was verified Cybersecurity control and management as recommended in FDA.

5.8. Substantial Equivalence

CUVIS-spine, a proposed device, is equivalent to CUVIS-spine(K201569) as a whole, and some characteristics are equivalent to Excelsius GPS^{TM}(K171651).

CUVIS-spine is not based on a new technology. The differences between CUVIS-spine and the predicate device would not affect the safety, effectiveness, and essential performance. Thus, subject device CUVIS-spine is concluded to be substantially equivalent to the predicate device.

5.9. Conclusions

On the basis of the information provided in this Summary, CUREXO, INC. believes that CUVIS-spine is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.