June 25, 2026

Alphatec Spine, Inc.
% Unnati Bhuptani
Manager, Regulatory Affairs
1950 Camino Vida Roble
CARLSBAD, CA 92008

Re: K253216
Trade/Device Name: IntraOp Alignment System; CONTOUR3D Bending System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: SIN, OWB, JAA, LLZ
Dated: September 26, 2025
Received: September 29, 2025

Dear Unnati Bhuptani:

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,

Lu Jiang

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Assistant Director
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Office of Product Evaluation and Quality
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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)*
K253216

Device Name
IntraOp Alignment System,
CONTOUR3D Bending System

Indications for Use *(Describe)*
IntraOp Alignment System:

The IntraOp Alignment System is intended for use in applications where a mobile C-arm fluoroscope is incorporated to aid in diagnosis and treatment during spinal surgery.

The IntraOp Alignment System is also intended to assist healthcare professionals in viewing, storing, and measuring spinal alignment assessment images at various time points during surgery, as well as planning spinal surgical procedures, including a user-defined, patient-specific rod plan during surgery.

The IntraOp Alignment System is intended for adults and pediatrics.

CONTOUR3D Bending System:

The CONTOUR3D Bending System is intended to intraoperatively bend compatible Alphatec spinal rods by generating and executing bending instructions in accordance with a user-defined rod plan and data imported from the IntraOp Alignment 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.

This 510(k) summary of substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER:

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Alphatec Spine, Inc.
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Date Summary Prepared: June 23, 2026

B. DEVICES

IntraOp Alignment System

Trade Name:	IntraOp Alignment System
Common or Usual Name:	Interventional Fluoroscopic X-ray System Image-Intensified Fluoroscopic X-ray System
Classification Name:	(21 CFR §892.1650)
Regulatory Class:	Class II
Product Code:	OWB
Secondary Codes:	JAA, LLZ

CONTOUR3D Bending System

Trade Name:	CONTOUR3D Bending System
Common or Usual Name:	Automated Intraoperative Spinal Rod Bending System
Classification Name:	Thoracolumbosacral Pedicle Screw System (21 CFR §888.3070)
Regulatory Class:	Class II
Product Code:	SIN
Secondary Codes:	OWB

C. LEGALLY MARKETED PREDICATE DEVICES

IntraOp Alignment System

Primary Predicate:

Trade Name:	IntraOp Alignment System
510(k) Number:	K240199
510(k) Clearance Date:	May 22, 2024
Common or Usual Name:	Interventional Fluoroscopic X-ray System
Classification Name:	Image-Intensified Fluoroscopic X-ray System (21 CFR §892.1650)
Regulatory Class:	Class II
Product Code:	OWB
Secondary Codes:	JAA, LLZ

CONTOUR3D Bending System:

Primary Predicate:

Trade Name:	Invictus Spinal Fixation System
510(k) Number:	K232275
510(k) Clearance Date:	September 27, 2023
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System (21 CFR §888.3070)
Regulatory Class:	Class II
Product Code:	NKB
Secondary Codes:	KWQ, OUR, KWP, PML

Reference Device:

510(k)	Product Name	Product Code	Clearance Date
K230195	Neo ADVISE Software	OLO	03/08/2024
K192938	Invictus™ Spinal Fixation System	NKB, KWP	12/12/2019
K161363	Arsenal Spinal Fixation System	NKB, KWP, MNH, MNI, OSH	06/10/2016

D. DEVICE DESCRIPTION

IntraOp Alignment System

The subject *IntraOp Alignment (IOA) System* consists of the following system components: an optical tracking sensor, touchscreen computer, a mobile cart (stand) including an

extension arm, and an electronics box with frame grabber, ports for video cables, power cables, and external storage devices.

The subject *IntraOp Alignment System is* a software-based system that from one end interfaces with a mobile C-arm fluoroscope through a video cable and a frame capture device to receive fluoroscopic images as they are acquired, and from the other end connects to an optical position tracking sensor to track the position and orientation of a C-arm in real-time. By using subject *IntraOp Alignment System* with mobile C-arm fluoroscopy equipment, the user can combine multiple fluoroscopic images, as they are being acquired, into stitched long bi-planar radiographic images for intraoperative visualization, assessment, and rod planning. The user is required to identify the location of the spine in both bi-planar views to scale the image content and provide information regarding the depth of the operative anatomy. The user can then use the measurement tools available on the subject *IntraOp Alignment System* to visualize and assess the spinal alignment for intraoperative planning of the surgical procedure. In addition, the subject *IntraOp Alignment System* allows users to create rod plans intraoperatively and is capable of exporting those plans to the *CONTOUR3D Bending System* for the rods to be bent. The surgeon's rod contour specifications can be informed through multiple inputs including intraoperative fluoroscopic imaging providing the surgeon with a visualization of the patient's anatomy, implant locations, and spinopelvic alignment measurements, both current and planned, to create a patient specific rod plan.

The subject *IntraOp Alignment System* has an optional capability to connect to a hospital-provided Wi-Fi to import pre-operatively planned alignment parameters from an Alphatec cloud database. The subject *IntraOp Alignment System* can then export those pre-operative rod plans to the *CONTOUR3D Bending System* for the rods to be bent. The subject *IntraOp Alignment System* also has the capability to export the post-operative alignment parameters to the cloud database.

The subject IntraOp Alignment System sits outside the sterile field and is provided non-sterile. The subject device is intended for use by trained healthcare professionals and appropriately trained non-clinical personnel. The subject device is intended for use in operating room environments of hospitals and surgical centers. System setup may be performed by trained non-clinical personnel.

This submission seeks to establish that the *IntraOp Alignment System* is substantially equivalent to the primary predicate, *IntraOp Alignment System* (K240199) with respect to indications for use (IFU), intended use, technology, and performance specifications.

CONTOUR3D Bending System

The *CONTOUR3D Bending System* consists of a mobile cart which includes the display, keypad, bending hardware, and internal components including the computer, control electronics, and rod positioning/bending motors.

The *CONTOUR3D Bending System* is a new automated electromechanical device that bends a posterior spinal fixation rod to a surgeon's specifications intraoperatively based on inputs from the IntraOp Alignment application. The *CONTOUR3D Bending System* maintains a sterile barrier with the rod while the automated bending provides reproducible outputs based on the *IntraOp Alignment System* generated patient specific rod plan. Please refer to additional information in the CONTOUR3D Bending System User Manual on pedicle screw system rods that are compatible with the CONTOUR3D Bending System.

The subject *CONTOUR3D Bending System* is provided non-sterile and is non-patient contacting. The subject *CONTOUR3D Bending System* is covered with a custom OEM drape to maintain a sterile barrier with the rod. The subject device is intended for use by trained healthcare professionals and appropriately trained non-clinical personnel. The subject devices are intended for use in operating room environments of hospitals and surgical centers. System setup may be performed by trained non-clinical personnel.

This submission seeks to establish that the *CONTOUR3D Bending System* is substantially equivalent to the primary predicate, *Invictus Spinal Fixation System* (K232275) with respect to indications for use (IFU), intended use, technology, and performance specifications.

E. INDICATIONS FOR USE

IntraOp Alignment System

The IntraOp Alignment System is intended for use in applications where a mobile C-arm fluoroscope is incorporated to aid in diagnosis and treatment during spinal surgery.

The IntraOp Alignment System is also intended to assist healthcare professionals in viewing, storing, and measuring spinal alignment assessment images at various time points during surgery, as well as planning spinal surgical procedures, including a user-defined, patient-specific rod plan during surgery.

The IntraOp Alignment System is intended for adults and pediatrics.

CONTOUR3D Bending System

The CONTOUR3D Bending System is intended to intraoperatively bend compatible Alphatec spinal rods by generating and executing bending instructions in accordance with a user-defined rod plan and data imported from the IntraOp Alignment System.

F. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject devices were compared to the predicate device in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. Any technological differences within this 510(k), between the subject devices and the predicate devices, does not impact substantially equivalence, or safety and effectiveness. ***Table 1*** and ***Table 2*** below provides a detailed analysis of the substantial equivalence of the device characteristics.

Table 1: Comparison for Substantial Equivalence: IntraOp Alignment System

Attribute	Predicate Device	Subject Device	SE Discussion
	IntraOp Alignment System (K240199)	**IntraOp Alignment System**	
Indications for Use	The IntraOp Alignment System is intended for use in applications where a mobile C-arm fluoroscope is incorporated to aid in diagnosis and treatment during spinal surgery. The IntraOp Alignment System is intended to assist healthcare professionals in viewing, storing and measuring spinal alignment assessment images at various time points during surgery as well as planning spinal surgical procedures. The IntraOp Alignment System is intended for use with patients aged 18 years or older.	The IntraOp Alignment System is intended for use in applications where a mobile C-arm fluoroscope is incorporated to aid in diagnosis and treatment during spinal surgery. The IntraOp Alignment System is also intended to assist healthcare professionals in viewing, storing, and measuring spinal alignment assessment images at various time points during surgery, as well as planning spinal surgical procedures, including a user-defined, patient-specific rod plan during surgery. The IntraOp Alignment System is intended for adults and pediatrics..	**The indications for use of the subject IntraOp Alignment System is the same as the primary predicate, IntraOp Alignment System, with the addition of rod planning. In addition, this 510(k) submission also seeks clearance for expanded intended patient population.**
Regulation Number	§892.1650;	§892.1650;	**Same as primary predicate, IntraOp Alignment System (K240199)**
Product Code	OWB, JAA, LLZ	OWB, JAA, LLZ	**Same as primary predicate, IntraOp Alignment System (K240199)**
Device Class	II	II	**Same as primary predicate, IntraOp Alignment System (K240199)**
Device Classification Name	Image-Intensified Fluoroscopic X-ray System	Image-Intensified Fluoroscopic X-ray System	**Same as primary predicate, IntraOp Alignment System (K240199)**
Device Functionalities	**Image Acquisition, Processing, Stitching, and Display:**	**Image Acquisition, Processing, Stitching, and Display:**	**The subject device has the same function as the primary predicate,**

Attribute	Predicate Device	Subject Device	SE Discussion
	IntraOp Alignment System (K240199)	**IntraOp Alignment System**	
	• Software based system that from one end interfaces with a mobile C-arm fluoroscope through a video cable and a frame capture device to receive fluoroscopic images as they are acquired. • As the images are being acquired, the user of the system can combine multiple fluoroscopic images, into stitched long bi-planar radiographic images for intraoperative visualization and spinal alignment assessments. • Serves only as an image display which is in addition to the fluoroscope's standard image display device. Device is passive, in that the operation depends only on the video output of the fluoroscope, and it does not transmit any signals or images to the fluoroscope. **Evaluation (Planning):** • **Spinal Alignment Measurements:** o After bi-planar images are acquired, they are calibrated by the user using the established tools available on IntraOp Alignment System software. o The user can place measurement tools for spinal alignment assessments.	• Software based system that from one end interfaces with a mobile C-arm fluoroscope through a video cable and a frame capture device to receive fluoroscopic images as they are acquired. • As the images are being acquired, the user of the system can combine multiple fluoroscopic images, into stitched long bi-planar radiographic images for intraoperative visualization and spinal alignment assessments. • Serves only as an image display which is in addition to the fluoroscope's standard image display device. Device is passive, in that the operation depends only on the video output of the fluoroscope, and it does not transmit any signals or images to the fluoroscope. **Evaluation (Planning):** • **Spinal Alignment Measurements:** o After bi-planar images are acquired, they are calibrated by the user using the established tools available on IntraOp Alignment System software. o The user can place measurement tools for spinal alignment assessments.	**IntraOp Alignment System (K240199) except for the rod planning feature. However, completed verification and validation testing successfully demonstrates that the new rod planning feature does not affect the safety and effectiveness of the device and can be considered substantially equivalent to the predicate device.**

Attribute	Predicate Device	Subject Device	SE Discussion
	IntraOp Alignment System (K240199)	**IntraOp Alignment System**	

		• **Rod Planning:**
		  ○ Once the bi-planar images are calibrated by the user, using the rod planning tool on the evaluation screen, the user has the ability to select rod parameters, place and adjust one or more rods on the image
		  ○ User also has the ability to import rod plans from the ATEC Cloud database and place them over the bi-planar image. However, these imported rod plans cannot be edited.
		  ○ Rod plan coordinates are generated by the system though user input, and transmitted to the bender	

C-arm Tracking	• When tracking is enabled, will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. • When tracking is enabled, requires hardware components in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. • When tracking is enabled, requires the use of an off-the-shelf tracking system in order to track the 6 DOF location of	• IntraOp Alignment System uses off-the-shelf tracking sensor and reflective tracking markers to track the 6 DOF location of the C-arm relative to tracking sensor. • The reflective tracking markers are attached on the mobile C-arm and are registered and calibrated on the IntraOp Alignment System after its initial application on the C-arm. • The IntraOp Alignment System GUI guides the user regarding the placement of the C-arm over the	**Substantially Equivalent.**

Attribute	Predicate Device	Subject Device	SE Discussion
	IntraOp Alignment System (K240199)	**IntraOp Alignment System**	
	the C-arm relative to the operating table. • When tracking is enabled, visual cues are provided which help guide the user in positioning the C-arm back to where a prior Baseline was taken.	operative anatomy and tracks the C-arm position relative to the tracking sensor using the reflective markers.	
Tracking Options	• Optical	• Optical	**Substantially Equivalent**
Algorithms	• Image quality improvement by distortion removal using C-Arm calibration data • Image stitching using C-Arm position coordinates • Depth correction based on user input • Various spinal assessment algorithms	• Image quality improvement by distortion removal using C-Arm calibration data • Image stitching using C-Arm position coordinates • Depth correction based on user input • Various spinal assessments including rod planning algorithms	**The subject device has the same algorithms as the primary predicate, IntraOp Alignment System (K240199), except for the rod planning algorithm. However, completed verification and validation testing successfully demonstrates that the new rod planning algorithm does not affect the safety and effectiveness of the device and can be considered substantially equivalent to the predicate device.**

Table 2: Comparison of Substantial Equivalence: CONTOUR3D Bending System

Attribute	Predicate Device	Reference Device	Subject Device	SE Discussion
	Invictus Spinal Fixation System (K232275)* ***Note: Only characteristics relevant to Pre-Bent Rods are included.**	**Neo ADVISE Software (K230195)**	**CONTOUR3D Bending System**	
Regulation	§888.3070	§882.4560	§888.3070	**Same as the predicate, Invictus Spinal Fixation System (K232275)**
Classification Name	Thoracolumbosacral Pedicle Screw System	Stereotaxic Instrument	Thoracolumbosacral Pedicle Screw System	**Same as the predicate, Invictus Spinal Fixation System (K232275)**
Product Code	NKB	OLO	Primary: SIN Secondary Code: OWB	**New product code under the same regulation as predicate.**
Spinal Rod Material	Pre-Bent Rods: • Titanium alloy (Ti-6Al-4V ELI) per ASTM F136 • Commercially pure titanium (CP Ti Grade 2) per ASTM F67 • Cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537	Unknown	Compatible Rod Material: • Titanium alloy (Ti-6Al-4V ELI) per ASTM F136 • Cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537	**Same as the predicate, Invictus Spinal Fixation System (K232275)**
Spinal Rod Diameter	Pre-Bent Rods: • 5.5 mm • 6.0 mm	Unknown	Compatible Rod Diameter: • 5.5 mm • 6.0 mm	**Same as the predicate, Invictus Spinal Fixation System (K232275)**
Spinal Rod Length	Pre-Bent Rods: 20-600 mm	Unknown	Compatible Rod Lengths: • Up to 400 mm (MIS) • Up to 495 mm (Open)	**Same as the predicate, Invictus Spinal Fixation System (K232275)**

Attribute	Predicate Device	Reference Device	Subject Device	SE Discussion
	Invictus Spinal Fixation System (K232275)* ***Note: Only characteristics relevant to Pre-Bent Rods are included.**	**Neo ADVISE Software (K230195)**	**CONTOUR3D Bending System**	
Rod Radii (Bends)	• Lordotic Rods: R114 and R230 • Z Rods: R10 • S Rods: R70, R180, R510 • J Rods: R70, R180 • Patient-Specific Rods: R15.45 - R ∞ (straight line)	Unknown	R11.5mm	**Bend Radius of the subject Contour3D System fall within the range of the predicate, Invictus Spinal Fixation System (K232275)**
Rod Angles (Bends)	• Lordotic Rods: N/A • Z Rods: 45° • S Rods: N/A • J Rods: N/A • Patient-Specific Rods: 0° - 45°	Unknown	0° - 30°	**Bend Angles of the subject Contour3D System fall within the range of the predicate, Invictus Spinal Fixation System (K232275)**
Rod Bending Procedure Location	Manufacturing Facility	N/A	Operating Room	**Substantially equivalent to Invictus Spinal Fixation System (K232275). While the rod bending procedure location is different between the subject and predicate device, the successful verification and validation activities demonstrate that this difference does not raise new questions of safety and effectiveness**

G. PERFORMANCE DATA

Nonclinical performance testing demonstrates that the subject *IntraOp Alignment System and CONTOUR3D Bending System* meets the functional, system, and software requirements. The following testing was conducted:

- System-level accuracy testing with the following acceptance criteria:
  - Rod Planning and Bending:
    - Maximum local deviation ≤ 3.5 mm
    - RMSE for entire rod ≤ 5.0 mm.
  - Spinal Alignment Measurements:
    - Angles: < 4 degrees
    - Distance: < 5 mm (for pediatrics: < 3 mm)
- Verification of the workflow to confirm that the system performs according to specifications.
- Verification testing to verify that the following features: image stitching, C-arm tracking, rod planning and rod bending meet performance specifications.
- Usability Evaluation.
- Sterilization Evaluation
- Biocompatibility Evaluation
- Cybersecurity Testing including penetration and vulnerability testing

EMC and Electrical Safety Testing of the *IntraOp Alignment System and CONTOUR3D Bending System* was performed to ensure all functions of the system and its components/accessories are electrically safe and comply with recognized electrical safety standards.

H. CONCLUSION

The information provided in this submission demonstrates that the subject device does not pose additional risk to safety and effectiveness when compared to the predicate device. The subject devices, *IntraOp Alignment System and CONTOUR3D Bending System*, are substantially equivalent to the primary predicate, *IntraOp Alignment System* (K240199) and *Invictus Spinal Fixation System* (K232275), respectively.