May 22, 2024

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

Re: K240199
Trade/Device Name: IntraOp Alignment System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, LLZ
Dated: January 24, 2024
Received: April 22, 2024

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 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240199

Device Name
IntraOp Alignment System

Indications for Use *(Describe)*
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.
The IntraOp Alignment System is intended for use with patients aged 18 years and older.

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.

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K240199 - 510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER:

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Alphatec Spine, Inc.
Contact Phone: (760) 356-6711

Date Summary Prepared: January 24, 2024

B. DEVICE

Trade Name:	IntraOp Alignment System
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
Subsequent Codes:	JAA, LLZ

C. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate

Trade Name:	Nuvasive® LessRay® with Enhanced Tracking
510(k) number:	K170800
510(k) Clearance Date:	August 18, 2017
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
Subsequent Codes:	JAA, LLZ

Additional Predicate

Trade Name:	ATEC Alignment App
510(k) number:	K211987
510(k) Clearance Date:	October 29, 2021
Common or Usual Name:	System, Image Processing, Radiological

Classification Name:	Medical image management and processing system (21 CFR §892.2050)
Regulatory Class:	Class II
Product Code:	LLZ

Reference Devices:

Trade Name:	NuVasive® NuvaLine®
510(k) number:	K192435
510(k) Clearance Date:	September 5, 2019
Common or Usual Name:	System, Image Processing, Radiological
Classification Name:	Medical image management and processing system (21 CFR §892.2050)
Regulatory Class:	Class II
Product Code:	LLZ

D. DEVICE DESCRIPTION

The subject *IntraOp Alignment (IOA) System* consists of 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* along the side of mobile C-arm fluoroscopy equipment, the user of the system can combine multiple fluoroscopic images, as they are being acquired, into stitched long bi-planar radiographic images for intraoperative visualization and assessment. 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.

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 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 clinical and 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, *Nuvasive® LessRay® with Enhanced Tracking* (K170800), and additional predicate *ATEC Alignment App* (K211987) with respect to indications for use (IFU), intended use, technology, and performance specifications.

E. 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 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.

The IntraOp Alignment System is intended for use with patients aged 18 years and older.

F. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject device was 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 device and the predicate device, does not impact substantially equivalence, or safety and effectiveness. ***Table 1*** below provided a detailed analysis of the substantial equivalence of the following device characteristics: indications for use, device functionalities, C-arm tracking, algorithms and accuracy specifications.

Table 1: Comparison for Substantial Equivalence

Attribute	Predicate Devices		Reference Device	Subject Device	SE Discussion
	Nuvasive® LessRay® with Enhanced Tracking (K170800)	**ATEC Alignment App (K211987)**	**NuVasive® NuvaLine® (K192435)**	**IntraOp Alignment System**	
Indications for Use	NuVasive® LessRay® with Enhanced Tracking is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.	The ATEC Alignment App assists healthcare professionals in viewing, measuring, and storing images as well as planning orthopedic surgeries. The app allows the healthcare professional to perform generic and specialty measurements of the images, and to plan surgical procedures. The app includes tools for measuring anatomical components for implant selection and offers the possibility to share data among ATEC Alignment App users. The app is for planning use only and is not intended for primary diagnostic use.	NuVasive NuvaLine is a medical device software application intended to assist healthcare professionals in capturing, viewing, measuring, and storage and distribution of spinal alignment assessment images at various time points in patient care. Online synchronization of the database allows healthcare professionals and service providers to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on various platforms. Clinical judgment and experience are required to properly use the software.	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. The IntraOp Alignment System is intended for use with patients aged 18 years and older.	**The subject device indications for use are same as the primary predicate, Nuvasive® LessRay® with Enhanced Tracking (K170800) for the image stitching functionality. The indications for use for use are also identical to the additional predicate ATEC Alignment App (K211987) for the spinal alignment assessments functionality. Completed V&V testing successfully demonstrated that the risks related to the differences in the indications for use between the subject device and primary predicate have been mitigated and do not affect the safety and effectiveness of the device. Therefore, the subject device can be considered substantially equivalent to the primary predicate, Nuvasive® LessRay® with Enhanced Tracking (K170800) and additional predicate, ATEC Alignment App (K211987).**
Regulation Number	§892.1650	§892.2050	§892.2050	§892.1650;	**Same**
Product Code	OWB, JAA, LLZ	LLZ	LLZ	OWB, JAA, LLZ	**Same**
Device Class	II	II	II	II	**Same**
Device Classification Name	Interventional Fluoroscopic X-Ray System	System, Image Processing, Radiological	System, Image Processing, Radiological	Interventional Fluoroscopic X-Ray System	**Same**
Device Functionalities	**Image Acquisition, Enhancement and Display :** • Software based device used to provide computer display systems interfaced to fluoroscope through a video cable. The images produced by the fluoroscope are transmitted through a cable to a frame capture board in the computer where the images are enhanced and then displayed on the monitor. • Enhanced images are displayed on a computer monitor at the same time that the corresponding original	**Measurement:** • Spinal alignment assessments of images	**Measurement:** • Spinal alignment assessments of images	**Image Acquisition, Processing, Stitching, and Display:** • 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	**Substantially Equivalent. The image stitching feature of the subject device is similar in function to the primary predicate, Nuvasive® LessRay® with Enhanced Tracking (K170800). The visualization and spinal alignment assessment feature of the subject device is similar in function to the additional predicate, ATEC Alignment App (K211987).**

Attribute	Predicate Devices		Reference Device	Subject Device	SE Discussion
	Nuvasive® LessRay® with Enhanced Tracking (K170800)	**ATEC Alignment App (K211987)**	**NuVasive® NuvaLine® (K192435)**	**IntraOp Alignment System**	
	image is displayed on the fluoroscope monitor(s). • 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.			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. **Spinal Alignment Measurements:** • After bi-planar images are acquired, they are calibrated by the user using the established tools available on IntraOp Alignment System software. • The user can place measurement tools for spinal alignment assessments.	
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 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.	N/A	N/A	• 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 operative anatomy and tracks the C-arm position relative to the tracking sensor using the reflective markers.	**Substantially Equivalent.**
Tracking Options	• Electromagnetic or optical	N/A	N/A	• Optical	**Substantially Equivalent**
Algorithms	• Image quality improvement using averaging algorithm	Patient parameters and calculations based on published literature	Various spinal assessment algorithms	• Image quality improvement by distortion removal using C-Arm calibration data	**Substantially Equivalent. The image stitching algorithm of the subject device is similar in function to the primary**

Attribute	Predicate Devices		Reference Device	Subject Device	SE Discussion
	Nuvasive® LessRay® with Enhanced Tracking (K170800)	**ATEC Alignment App (K211987)**	**NuVasive® NuvaLine® (K192435)**	**IntraOp Alignment System**	
	• Contrast and brightness enhancement with simultaneous reduction of random noise			• Image stitching using C-Arm position coordinates • Depth correction based on user input • Various spinal assessment algorithms	**predicate, Nuvasive® LessRay® with Enhanced Tracking (K170800). The spinal alignment assessment algorithm of the subject device is similar in function to the additional predicate, ATEC Alignment App (K211987).**

G. PERFORMANCE DATA

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

- Verification testing to confirm that the system meets the accuracy specifications
- 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 and spinal alignment measurements meet performance specifications

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

Clinical Information
Determination of substantial equivalence is not based on an assessment of clinical performance data.

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 device, *IntraOp Alignment System*, is substantially equivalent to the primary predicate, *Nuvasive® LessRay® with Enhanced Tracking* (K170800), and additional predicate *ATEC Alignment App* (K211987).