August 15, 2025

EOS imaging
℅ Mathilde Masurel
Design Quality and Regulatory Affairs Specialist
32 rue blanche
PARIS, 75009
FRANCE

Re: K251747
Trade/Device Name: VEA Align; spineEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: June 6, 2025
Received: June 6, 2025

Dear Mathilde Masurel:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251747

Device Name
VEA Align; spineEOS

Indications for Use *(Describe)*

VEA Align:
This cloud-based software is intended for orthopedic applications in both pediatric and adult populations.
2D X-ray images acquired in EOS imaging's imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment.
For additional assessment, alignment parameters compared to published normative values may be available.
This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older.
Clinical judgment and experience are required to properly use the software.

spineEOS:
spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.

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

1 SUBMITTER

EOS imaging
32 rue blanche
Paris, France 75009
Phone: +33 1 55 25 60 60
Fax: +33 1 55 25 60 61

Contact Person: Mathilde MASUREL
Design Quality and Regulatory Affairs Specialist
EOS imaging
Contact Phone: +33 1 55 25 60 60

Date Summary Prepared: August 15, 2025

2 DEVICES

2.1 VEA Align

Trade Name:	VEA Align
Common or Usual Name:	Cloud-based software
Classification Name:	Medical image management and processing system (21 C.F.R. 892.2050)
Regulatory Class:	Class II
Product Code:	QIH - Automated Radiological Image Processing Software

2.2 spineEOS

Trade Name:	spineEOS
Common or Usual Name:	Cloud-based software
Classification Name:	Medical image management and processing system (21 C.F.R. 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ - System, image processing, radiological

3 LEGALLY MARKETED PREDICATE DEVICE

510(k)	Product Name	Clearance Date
K240582	VEA Align; spineEOS	June 2024

4 DEVICE DESCRIPTION

4.1 VEA Align

VEA Align is a software indicated for assisting healthcare professionals with global alignment assessment through clinical parameters computation.

The product uses biplanar 2D X-ray images, exclusively generated by EOS imaging's EOS (K152788) and EOSedge (K202394) systems and generates an initial placement of the patient anatomic landmarks on the images using a machine learning-based algorithm. The user may adjust the landmarks to align with the patient's anatomy. Landmark locations require user validation. The clinical parameters communicated to the user are inferred from the landmarks and are recalculated as the user adjusts the landmarks. 3D datasets may be exported for use in spineEOS for surgical planning.

The product is hosted on a cloud infrastructure and relies on EOS Insight for support capabilities, such as user access control and data access. 2D X-ray image transmissions from healthcare institutions to the cloud are managed by EOS Insight. EOS Insight is classified as non-device Clinical Decision Support (CDS) software.

4.2 spineEOS

spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. spineEOS provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.

5 INDICATIONS FOR USE

5.1 VEA Align

This cloud-based software is intended for orthopedic applications in both pediatric and adult populations.

2D X-ray images acquired in EOS imaging’s imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment.

For additional assessment, alignment parameters compared to published normative values may be available.

This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older.

Clinical judgment and experience are required to properly use the software.

5.2 spineEOS

spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.

6 TECHNOLOGICAL COMPARISON TO PREDICATES

The subject devices were compared to their respective predicate devices in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. Any technological differences within this bundled 510(k), between the subject devices and the predicate devices, do not impact substantial equivalence, or safety and effectiveness.

Table 1: Summary of Predicate and Subject VEA Align Device Characteristics to Demonstrate Substantial Equivalence

Characteristic	Primary Predicate VEA Align (K240582)	Subject VEA Align	Substantially Equivalent?
Indications for Use	This cloud-based software is intended for orthopedic applications in both pediatric and adult populations. 2D X-ray images acquired in EOS imaging's imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment. For additional assessment, alignment parameters compared to published normative values may be available. This product serves as a tool to aid in the analysis of spinal deformities, degenerative diseases, lower limb alignment disorders, and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older. Clinical judgment and experience are required to properly use the software.	This cloud-based software is intended for orthopedic applications in both pediatric and adult populations. 2D X-ray images acquired in EOS imaging's imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment. For additional assessment, alignment parameters compared to published normative values may be available. This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older. Clinical judgment and experience are required to properly use the software.	**YES**
Contraindications	VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.	VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.).	**Similar** The change to the contraindications simply reflects an enhancement of the software flexibility without affecting its core design, safety, or intended use.
Regulatory Class/Code	Class II QIH (21 CFR 892.2050)	Class II QIH (21 CFR 892.2050)	**YES**

Characteristic	Primary Predicate VEA Align (K240582)	Subject VEA Align	Substantially Equivalent?
Device Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	**YES**
Operating System	Windows + MAC	Windows + MAC	**YES**
User Population	VEA Align Alignment Assessment mode is designed for surgeons and clinical staff, such as physician assistants, who have been trained to use the application. VEA Align 3D mode is designed for 3D Services team members.	VEA Align Alignment Assessment mode is designed for surgeons and clinical staff, such as physician assistants, who have been trained to use the application. VEA Align 3D mode is designed for 3D Services team members.	**YES**
Target Population	The device is indicated only for patients 7 years and older.	The device is indicated only for patients 7 years and older.	**YES**
Software Functionalities / Modalities	Global alignment assessments	Global alignment assessments	**YES**
	Includes landmarks associated with vertebral endplates needed to calculate coronal and sagittal clinical parameters. These landmarks are adjustable by the user.	Includes landmarks associated with vertebral endplates needed to calculate coronal and sagittal clinical parameters. These landmarks are adjustable by the user.	**YES**
	Includes landmarks associated with the pelvis and lower limbs needed to calculate coronal and sagittal clinical parameters. These landmarks are adjustable by the user.	Includes landmarks associated with the pelvis and lower limbs needed to calculate coronal and sagittal clinical parameters. These landmarks are adjustable by the user.	**YES**
	Provides normative values used to assess patients' global alignment	Provides normative values used to assess patients' global alignment	**YES**
	Provides color-coded clinical parameters to display variance from the defined normative values	Provides color-coded clinical parameters to display variance from the defined normative values	**YES**
Image Manipulation Functions	2D images display and basic manipulation (zoom, panning)	2D images display and basic manipulation (zoom, panning)	**YES**

Characteristic	Primary Predicate VEA Align (K240582)	Subject VEA Align	Substantially Equivalent?
Measurement Functions	Distances and Angles	Distances and Angles	**YES**
Algorithms	Patient-specific clinical parameters and calculations based on published literature.	Patient-specific clinical parameters and calculations based on published literature.	**YES**
3D Reconstruction Model	Alignment mode: The 3D model supports the initial placement of the patient anatomic landmarks on the images using a machine learning-based algorithm. It is not displayed to the user and as such it is not part of the device outputs. 3D mode: The 3D reconstruction model is deformed manually by the user through control points up to matching accurately the X-ray contours.	Alignment mode: The 3D model supports the initial placement of the patient anatomic landmarks on the images using a machine learning-based algorithm. It is not displayed to the user and as such it is not part of the device outputs. 3D mode: The 3D reconstruction model is deformed manually by the user through control points up to matching accurately the X-ray contours.	**YES**
User Interface	Computer	Computer	**YES**
Obtaining an image	Transferred from other devices	Transferred from other devices	**YES**
Software Environment	Cloud-based software	Cloud-based software	**YES**
Human Intervention for interpretation and manipulation of images	Required	Required	**YES**
Control of life-saving devices	None	None	**YES**

Table 2: Summary of Predicate and Subject spineEOS Device Characteristics to Demonstrate Substantial Equivalence

Characteristic	Primary Predicate spineEOS (K240582)	Subject Device spineEOS	Substantially Equivalent?
Indications for Use	spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.	spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.	**YES**
Contraindications	The surgical planning application is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.	The surgical planning application is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.	**YES**
Regulatory Class/Code	Class II LLZ (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	**YES**
Device Classification Name	System, image processing, radiological	System, image processing, radiological	**YES**
User Population	The surgical planning application can only be used by a trained user including: • Spine surgeons to define and validate the surgical plan. • EOS staff and implant distributors to define and save the optional pre-planning.	The surgical planning application can only be used by a trained user including: • Spine surgeons to define and validate the surgical plan. • EOS staff and implant distributors to define and save the optional pre-planning.	**YES**
Target Population	The product is recommended in the preoperative planning of primary and revision spine surgeries for: • Degenerative spine and adult spinal deformity. • Adolescent Idiopathic Scoliosis (AIS) patients.	The product is recommended in the preoperative planning of primary and revision spine surgeries for: • Degenerative spine and adult spinal deformity. • Adolescent Idiopathic Scoliosis (AIS) patients.	**YES**
Hardware and Software Requirement	**Web Browsers**:	**Web Browsers:**	**Similar** The modified spineEOS considers the last version of the

Characteristic	Primary Predicate spineEOS (K240582)	Subject Device spineEOS	Substantially Equivalent?
	• With Windows 10 or 11: Google Chrome in version 121 or higher, and Edge in version 121 or higher. • With Mac OS Monterey or Ventura: Google Chrome in version 121 or higher. **PC Configuration:** A stable high speed internet connection is required: DSL 100Mb/s connection or higher, Wi-Fi or Ethernet. **Screen Resolution:** The minimum screen resolution ensuring full display of the interface is 1366 x 768.	• With Windows 10 or 11: Google Chrome in version 130 or higher, and Edge in version 130 or higher. • With Mac OS 15 Sequoia: Google Chrome in version 130 or higher. **PC Configuration:** A stable high speed internet connection is required: DSL 100Mb/s connection or higher, Wi-Fi or Ethernet. **Screen Resolution:** The minimum screen resolution ensuring full display of the interface is 1366 x 768.	compatible web browsers and Mac Operating System.
Input Data	Patient's information X-rays images 3D landmarks of the spine generated from VEA Align	Patient's information X-rays images 3D landmarks of the spine generated from VEA Align	**YES**
Product Workflow	**3D spine reconstruction confirmation:** allow users to accept the 3D landmark input data or reject the 3D landmark input data and provide feedback on corrective adjustments. **Preoperative:** allow user to consult the preoperative state of the patient **Planning:** allow user to define patient specific surgical strategy **Rod**: allow user to define the design of rods	**3D spine and sacrum model reconstruction confirmation:** allow users to accept the 3D landmark input data or reject the 3D landmark input data and provide feedback on corrective adjustments. **Preoperative:** allow user to consult the preoperative state of the patient **Planning:** allow user to define patient specific surgical strategy **Rod:** allow user to define the design of rods The product includes two workflows according to the patient's age. • Pediatric workflow, for patient under 18 years old: The user has access to the 3D spine reconstruction confirmation and the Preoperative steps	**Similar** The workflow steps are identical compared to the predicate. The pediatric workflow prevents the user to have access to the planning and rod steps. However, the user still has access to the 3D spine reconstruction confirmation and the preoperative steps, with all the image manipulation functions available in these steps.

Characteristic	Primary Predicate spineEOS (K240582)	Subject Device spineEOS	Substantially Equivalent?
		• Adult workflow, for patient above 18 years old: The user has access to all the steps described above	
Tools Available for Planning	• Segmental Alignment • Interbody Implant • Osteotomy • Spondylolisthesis • Rod Curvature Management (From T1 to S1)	• Segmental Alignment • Interbody Implant • Osteotomy • Spondylolisthesis • Rod Curvature Management (From T1 to S2)	**Similar** Modified spineEOS allows the user to design a patient-specific rod until S2 vertebrae based on the landmarks generated by VEA Align.
Software Functionalities / Modalities	Obtains an image and 3D model transferred from other devices.	Obtains an image and 3D model transferred from other devices.	**YES**
	Provides normative values used to follow the impact of the planning on the patient alignment.	Provides normative values used to follow the impact of the planning on the patient alignment.	**YES**
	Provides color-coded clinical parameters to display variance from the defined normative values.	Provides color-coded clinical parameters to display variance from the defined normative values.	**YES**
	Requires human intervention for interpretation and manipulation of images.	Requires human intervention for interpretation and manipulation of images.	**YES**
Image Manipulation Functions	2D images and 3D spine display and basic manipulation (zoom, panning, angles measurements, plumbline, and possibility to add comments on the image).	2D images and 3D spine display and basic manipulation (zoom, panning, angles measurements, plumbline, and possibility to add comments on the image).	**YES**
Measurement Functions	Distances and Angles	Distances and Angles	**YES**.
User Interface	Computer	Computer	**YES**
Software Environment	Cloud-based software	Cloud-based software	**YES**
Clinical Parameters Computation	• Pelvic Tilt (PT) • Sacral Slope (SS) • Pelvic Incidence (PI) • Pelvic Obliquity (PO) • Sagittal Vertical Axis (SVA) • C7-CSL • PI-LL • T1 Pelvic Angle (TPA)	• Pelvic Tilt (PT) • Sacral Slope (SS) • Pelvic Incidence (PI) • Pelvic Obliquity (PO) • Sagittal Vertical Axis (SVA) • C7-CSL • PI-LL • T1 Pelvic Angle (TPA)	**Similar** Except for the addition of L1PA, T4PA, the axial rotation, disc height and disc segmental lordosis. L1PA and T4PA measure the same angle but taking respectively L1 and T4 instead of T1. The

Characteristic	Primary Predicate spineEOS (K240582)	Subject Device spineEOS	Substantially Equivalent?
	• Cobb Angle • Kyphosis/Lordosis Angle • Knee Flexion/Extension Angle • Lordosis Percentage Distributions • Spondylolisthesis grade (i.e., Slippage percentage)	• Cobb Angle • Kyphosis/Lordosis Angle • Knee Flexion/Extension Angle • Lordosis Percentage Distributions • Spondylolisthesis grade (i.e., Slippage percentage) • L1 Pelvic Angle (L1PA) • T4 Pelvic Angle (T4PA) • Axial rotation (not computed) • Disc height (anterior and posterior) • Disc segmental lordosis	subject device uses the same validated point as the predicate. The axial rotation is displayed based on the input data received from VEA Align. It is not computed at the planning step. Disc height and disc segmental lordosis are new clinical parameters linked to the disc. However, they aim to calculate distances (height) and angles (lordosis), same as the other existing clinical parameters.
Control of Life-Saving Devices	None	None	**YES**

7 PERFORMANCE DATA

Nonclinical performance testing performed on the subject devices, VEA Align and spineEOS, supports substantial equivalence to their respective predicate devices. The following V&V testing was performed:

A. Verifications activities cover the following:

- Design input review
- Unit testing
- Software integration
- System integration

B. AI validation performance test:
To assess the standalone performance of the AI algorithm of the VEA Align, the test was performed with:
    - A dedicated test data set containing different data from the training data set. Specifically, the test data set is not a sampling of the training data set, has never been used for the algorithm training or for tunning the algorithm and leakage between training and test data sets did not occur.
    - For each patient of this data set, a ground truth EOS 3DServices reconstruction (model) from sterEOS (K172346) that was available for comparison with VEA Align reconstruction generated by the AI algorithm.
    - A global acceptance criterion to assess the performance of the AI algorithm predictions regarding the ground truth.
    - Subgroup analyses to assess bias and generalizability.

Training data information

The training dataset remained the same as previously submitted for the predicate devices. The AI algorithm was trained using 10,376 X-ray images and a total of 5,188 corresponding 3D reconstructions. This training data set contained images which were collected from EOS (K152788) and EOSedge (K202394) systems at a variety of sites from 2007-2023. This population characteristics cover the intended use population. The data set ensures a variety of data for the different clinical metrics: scoliosis, postural balance, degenerative disease and spine surgery implant (preoperative and postoperative). The images were also acquired using different radiation exposure parameters and with different fields of view.

Testing data information

The testing data set consisted of 361 patients and the demographic characteristics cover the intended use population. The data set includes images from EOS (K152788) and EOSedge (K202394) systems.

Subgroup definition (generalizability)

Test data was divided according to the subgroups listed below. The subgroups are intended to demonstrate the generalizability of the algorithm.

- Demographics
  - Age
  - Gender
- Clinical Metrics
  - Spinal Deformity
    - Scoliosis severity
    - Postural balance severity
  - Degenerative Disease
  - Spine surgery implant status (preoperative and postoperative)
- Image Acquisition
  - Equipment model
  - Radiation exposure parameters
  - Field of view
- Data site location
  - Different US states

Acceptance Criteria

The acceptance criteria are used to characterize the performance of the AI algorithm feature. As such, the following acceptance criteria were defined:

- Median error ≤ 3 mm
- 3rd Quartile ≤ 5 mm

Testing summary

Testing showed that the subject device is equivalent to the predicate device. Direct comparison between skeletal landmark locations between the subject device and predicate device met acceptance criteria for algorithm performance.

Testing was performed over the whole population and for each sub-group mentioned before in order to prove the generalizability of the device performance across the different populations.

All the studies performed indicate acceptable performances of the algorithm for its intended population.

C. Validation activities also cover the following for both VEA Align and spineEOS:
   - Validation of the multifunctional requirements in terms of design.
   - Usability testing was performed to demonstrate that the subject devices can be used safely by assessing and mitigating usability risks.
   - Validation of the reproducibility and accuracy of clinical parameter outputs.

8 CONCLUSION

Based on the information provided in this 510(k) submission, it was determined that the subject devices, VEA Align and spineEOS, are substantially equivalent to the legally marketed predicate devices with regards to indications for use, intended use, design, technology, and performance.