June 25, 2024

EOS imaging
Moran Celestin
Design Quality and Regulatory Affairs Specialist
10 rue Mercoeur
Paris, 75011
France

Re: K240582
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: May 17, 2024
Received: May 17, 2024

Dear Moran Celestin:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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)*
K240582

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.

510(k) Summary / K240582

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
10 rue Mercoeur
Paris, France 75011
Phone: +33 1 55 25 60 60
Fax: +33 1 55 25 60 61

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

Date Summary Prepared: June 24, 2024

2 DEVICES

2.1 VEA Align

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

2.2 spineEOS

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

3 LEGALLY MARKETED PREDICATE DEVICES

3.1 VEA Align

510(k)	Product Name	Clearance Date
K231917	VEA Align (primary predicate)	January 2024
K172346	sterEOS (secondary predicate)	June 2018

3.2 spineEOS

510(k)	Product Name	Clearance Date
K232086	spineEOS	October 2023

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 VEA Portal 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 VEA Portal. VEA Portal is a Class I 510(k)-exempt device (LMD).

4.2 spineEOS

spineEOS is a software indicated for assisting healthcare professionals with preoperative planning of spine surgeries. EOS images (generated from EOS imaging's acquisition system) and associated 3D datasets are used as inputs of the software. The product manages clinical measurements and allows user to access surgical planning tools to define a patient specific surgical strategy. The product is indicated for adolescent and adult patients.

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, 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 (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
Indication 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.	The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general device for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system including interactive 2D measurement tools. When using 2D X-ray images obtained with the EOS imaging EOS system, sterEOS Workstation provides interactive 3D measurement tools: • To aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients. The 3D measurement tools include interactive analysis based either on identification of anatomical landmarks for postural assessment, or on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients	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.	**YES** Same as VEA Align.

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
	Clinical judgment and experience are required to properly use the software.	with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data for spine modeling. The model of bone structures is not intended for use to assess individual vertebral abnormalities and is indicated only for patients 7 years and older. For postural assessment, a set of comparative tools is provided allowing the comparison of performed measurements to reference values for patients over 18 years old. • To aid in the analysis of lower limbs alignment and related disorders and deformities based on angle and length measurements. The 3D measurement tools include interactive analysis based either on identification of lower limb alignment landmarks or as for the spine, on a model of bone structures derived from an a priori image data set. The model of bone structures is not intended for use to assess individual bone	Clinical judgment and experience are required to properly use the software.	

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
		abnormalities. The 3D package including model-based measurements and torsion angles is indicated only for patients 15 years or older. Only the 2D/3D ruler is indicated for measurements in patients younger than 15 years old.		
Contraindications	VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.	The 3D spine modeling software does not allow modeling of vertebrae with severe congenital deformities (e.g. hemivertebrae, spina bifida, etc.). The modeling of a spine that has a vertebrae with a congenital deformity may be generated leaving out the vertebrae with the congenital deformity. The 3D models delivered by the sterEOS software can only be used for diagnostic purposes with the corresponding 2D images. They are designed to display the spatial relationship between anatomical structures and are unable to highlight local bone alterations such as: • bones with significant changes in geometry following surgical intervention,	VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.	**YES** Same as VEA Align.

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
		• fractures, • osteophytes, • fibrocartilage calluses. The lower limb 3D model is based on an adult type and, as a result, is not suited to pediatric lower limb 3D reconstruction. 3D modeling can become inaccurate and even impossible when anatomical structures cannot be identified as such in the following cases: • prostheses or instruments masking or replacing anatomical markers, • certain pathological conditions that alter the bone composition, such as osteoporosis, • impossibility to differentiate the internal condyle from the external condyle or the internal tibial plate from the external tibial plate.		
Regulatory Class/Code	Class II QIH (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	Class II QIH (21 CFR 892.2050)	**YES**

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
Device Classification Name	Automated Radiological Image Processing Software	System, Image Processing, Radiological	Automated Radiological Image Processing Software	**YES**, Same as VEA Align.
Operating System	Windows + MAC	Windows	Windows + MAC	**YES**
User Population	VEA Align is designed for surgeons and clinical staff, such as physician assistants, who have been trained to use the application.	Clinicians (radiologists, orthopedists, radiographers), 3D Services persons, which have been trained to use the application.	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** Alignment Assessment mode is equivalent to predicate VEA Align and 3D Mode is equivalent to predicate sterEOS (3D Services users).
Target Population	The device is indicated only for patients 7 years and older.	3D measurement tools are used on adult and pediatric patients over 7 years of age who suffer from scoliosis and deformed spine pathology and for patients over 15 years of age with deformed lower limb pathology.	The device is indicated only for patients 7 years and older.	**YES** Same as VEA Align.
Software Functionalities / Modalities	Global alignment assessments	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.	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.	Includes landmarks associated with the pelvis and lower limbs needed to calculate coronal and sagittal clinical parameters.	Includes landmarks associated with the pelvis and lower limbs needed to calculate coronal and sagittal clinical parameters.	**YES**

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
	These landmarks are adjustable by the user.	These landmarks are adjustable by the user.	These landmarks are adjustable by the user.	
	Provides normative values used to assess patients' global alignment	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	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, distance, and angles measurements)	2D images display and basic manipulation (zoom, panning)	**YES** Same as VEA Align.
Measurement Functions	Distances and Angles	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.	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.	The 3D 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 mode outputs. 3D mode: The 3D reconstruction model is initialized by an AI algorithm and then deformed manually by the user through control points up to matching	**YES** Alignment Assessment mode is equivalent to predicate VEA Align. In the 3D mode, the 3D reconstruction model is an output of the device as for the secondary predicate, sterEOS. The difference between the secondary predicate sterEOS and the subject

Characteristic	Primary Predicate VEA Align (K231917)	Secondary Predicate sterEOS (K172346)	Subject VEA Align	Substantially Equivalent?
			accurately the X-ray contours. The 3D reconstruction model is an output of the 3D mode.	VEA Align is the automatic initialization using an AI algorithm for VEA Align 3D model reconstruction generation. This difference allows the user to gain time duringmanual adjustment. This difference does not prevent VEA Align from achieving its intended purpose and does not create a new risk in VEA Align. Therefore, this difference does not affect device safety or effectiveness.
User Interface	Computer	Computer	Computer	**YES**
Obtaining an image	Transferred from other devices	Transferred from other devices	Transferred from other devices	**YES**
Software Environment	Cloud-based software	Standalone	Cloud-based software	**YES** Same as VEA Align.
Human Intervention for interpretation and manipulation of images	Required	Required	Required	**YES**
Control of life-saving devices	None	None	None	**YES**

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

Characteristic	Predicate Device spineEOS (K232086)	Subject Device spineEOS	Substantially Equivalent?
Indications for Use	spineEOS software 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.	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** Despite different wording, the objective and intent of both devices are the same.
Contraindications	spineEOS is not intended to be used in the following cases: Patients under the age of 7. Patients with vertebrae with congenital deformities (e.g., hemivertebrae, spina bifida, etc.). The 3D models delivered by sterEOS can only be used for diagnostic purposes in association with the corresponding 2D images. They are intended for the visualization of the spatial relationship between anatomical structures and do not allow the identification of local bone alterations such as: Bones with a significant change in geometry following surgery, Fractures, Osteophytes Fibrocartilage calluses	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** The product's contraindications come from the device providing the input data.
Regulatory Class/Code	Class II LLZ (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	**YES**

Characteristic	Predicate Device spineEOS (K232086)	Subject Device spineEOS	Substantially Equivalent?
Device Classification Name	System, image processing, radiological	System, image processing, radiological	**YES**
User Population	spineEOS 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 device 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:** With Windows 10 or 11: Google Chrome in version 111 or higher, and Edge in version 111 or higher. With Mac OS Monterey or Ventura: Google Chrome in version 111 or higher, and Safari in version 16.2 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 1600 x 900.	**Web Browsers:** 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.	**YES** Safari has been removed for the subject device
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	**Model Validation:** allow users to validate or reject the 3D landmarks.	**3D spine reconstruction confirmation:** allow users to accept the 3D spine representation and associated landmarks, or reject the 3D spine	**YES**. The name of the "Model Validation" step has been changed in the subject

Characteristic	Predicate Device spineEOS (K232086)	Subject Device spineEOS	Substantially Equivalent?
	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	representation and associated landmarks 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	spineEOS to conform with the type of input data
Tools Available for Planning	Segmental Alignment Interbody Implant Osteotomy Spondylolisthesis Rod Curvature Management	Segmental Alignment Interbody Implant Osteotomy Spondylolisthesis Rod Curvature Management	**YES**
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 model display and basic manipulation (zoom, panning, and 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** The wording referring to the representation of the spine in 3D differs from the predicate to more precisely describe the spine representation. However, it remains the same between the predicate and the subject spineEOS.
Measurement Functions	Distances and Angles	Distances and Angles	**YES**.
User Interface	Computer	Computer	**YES**

Characteristic	Predicate Device spineEOS (K232086)	Subject Device spineEOS	Substantially Equivalent?
Software Environment	Cloud-based software	Cloud-based software	**YES**
Clinical Parameters Computation	Pelvic Tilt (PT) Sacral Slope (SS) Pelvic Incidence (PI) Pelvic Obliquity (PO) Pelvic Axial Rotation Sagittal Vertical Axis (SVA) C7-CSL PI-LL T1 Pelvic Angle (TPA) Cobb Angle Kyphosis/Lordosis Angle Knee Flexion/Extension Angle Lordosis Percentage Distributions Spondylolisthesis grade (i.e., Slippage percentage)	Pelvic Tilt (PT) Sacral Slope (SS) Pelvic Incidence (PI) Pelvic Obliquity (PO) Sagittal Vertical Axis (SVA) C7-CSL PI-LL T1 Pelvic Angle (TPA) Cobb Angle Kyphosis/Lordosis Angle Knee Flexion/Extension Angle Lordosis Percentage Distributions Spondylolisthesis grade (i.e., Slippage percentage)	**YES** Pelvic Axial Rotation has been removed from the subject device. Cotyle Axis allows determination of the patient frame in which clinical parameters are computed. Pelvic Axial Rotation is computed based on Cotyle Axis. So, in the patient frame the value is always 0 for this parameter.
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 on both subject devices:

A. Verifications activities cover the following:

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

B. Verification 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 was 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 Workstation (K172346)that was available for comparison with the 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 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 538 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:
  - Without spinal conditions
  - Spinal Deformity
    - Scoliosis severity
    - Postural balance severity
  - Degenerative Disease
  - Spine Surgery Implant (preoperative and postoperative)
- Image Acquisition
  - Equipment model
  - Radiation exposure parameters
  - Field of view
- Data Site Location:
  - US vs. OUS
  - Different US states

A randomized sampling was used for each category to include an equal number of cases within each subgroup.

Acceptance criteria

For spinal landmark accuracy the metric computed was the Euclidean distance and for spinal mesh accuracy the metric computed was point to surface distance. The acceptance criteria for both landmark and mesh accuracy errors was defined as:

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

Testing summary

Direct comparison between skeletal landmark locations between the subject device and predicate VEA align (K231917) met acceptance criteria for algorithm performance.

Direct comparison between additional spinal landmarks location between the subject device and predicate sterEOS Workstation (K172346) met acceptance criteria for algorithm performance.

Direct comparison between the 3D thoraco-lumbar mesh from subject device and the 3D thoraco-lumbar mesh from the predicate sterEOS Workstation (K172346) met the acceptance criteria demonstrating substantial equivalence of the subject device.

All those tests were 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 cover the following:

- 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.