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

January 5, 2024

Re: K231917
Trade/Device Name: VEA Align
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 4, 2023
Received: December 4, 2023

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231917

Device Name
VEA Align

Indications for Use *(Describe)*
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.

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

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Date Summary Prepared: January 5, 2024

2 DEVICE

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

3 LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Name	Clearance Date
K172346	sterEOS Workstation	June 2018

4 DEVICE DESCRIPTION

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.

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).

5 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.

6 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 substantial equivalence, or safety and effectiveness.

Table 5-1: Comparison for Substantial Equivalence

Characteristic	Predicate Device sterEOS Workstation 510(k): K172346	Subject Device VEA Align	Substantially Equivalent?
Indication for Use	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 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.	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.	Yes, both devices are indicated for the display and digital processing of 2D X-ray images. Both devices are indicated for the same type of disease, i.e., in the case of diseases that have an impact on the patient's global alignment. The information provided by both products is to be used as a diagnostic aid for the user.

Characteristic	Predicate Device sterEOS Workstation 510(k): K172346	Subject Device VEA Align	Substantially Equivalent?
	• 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 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.		
Regulatory Class/Code	Class II LLZ (21 CFR 892.2050)	Class II QIH (21 CFR 892.2050)	The product code for the predicate device is LLZ. The QIH product code was created after clearance of the predicate device and appears to be a better match for VEA Align than LLZ. VEA Align employs machine learning based algorithms that were trained from data generated by EOS Imaging's imaging systems to automate the radiological image processing and analysis.
Device Classification Name	System, Image Processing, Radiological	Automated Radiological Image Processing Software	Yes, both devices are classified under 21 CFR 892.2050.
Operating System	Windows	Windows + MAC	Yes, the subject device is compatible with windows like the predicate device. It is also

Characteristic	Predicate Device sterEOS Workstation 510(k): K172346	Subject Device VEA Align	Substantially Equivalent?
			compatible with the MAC operating system.
User Population	Clinicians (radiologists, orthopedists, radiographers), 3DServices persons, which have been trained to use the application	Surgeons and clinical staff (physician assistants) that have been trained to use the application	Yes, while the user population is slightly different, the inclusion of surgeons and clinical staff do not affect device safety or effectiveness.
Target Population	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.	Similar. The subject device is dedicated to understanding the global alignment of patients, spine and lower limb included. The 15-year-old limitation of the predicate device was attached to workflow dedicated specifically to lower limbs only. This workflow is not present in the subject device. This difference does not affect device safety or effectiveness.
Software Functionalities / Modalities	Global alignment assessments	Global alignment assessments	Yes
Image Manipulation Functions	2D images display and basic manipulation (zoom, panning, distance, and angles measurements)	2D images display and basic manipulation (zoom, panning)	Similar. In VEA Align the user does not have the possibility to make additional measurements after reviewing the alignment provided by the software. The removal of this function does not prevent VEA Align from achieving its intended purpose and does not create a new risk in VEA Align. The computation of the specific clinical parameters claimed in the VEA Align User Manual is not impacted by the removal of this function. This function is not linked to the

Characteristic	Predicate Device sterEOS Workstation 510(k): K172346	Subject Device VEA Align	Substantially Equivalent?
			performance of VEA Align. Consequently, there is no impact on the effectiveness of VEA Align.
Measurement Functions	Distances and Angles	Distances and Angles	Yes
3D Model	The 3D model is deformed manually by the user through control points up to matching accurately the X-ray contours. This deformation is performed by using the common linear least squares estimation algorithm.	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.	In VEA Align, the 3D model is not visible to the user and the latter cannot interact with it. The 3D model is not part of the device outputs contrary to the predicate device. 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	Yes
Software Environment	Standalone	Cloud-based software	Yes, the difference regarding the software environment does not introduce new risks, or impact existing risks. Therefore, this difference does not affect device safety or effectiveness.

7 PERFORMANCE DATA

Nonclinical performance testing performed on the subject device, VEA Align, supports substantial equivalence to the predicate device. The following V&V testing was performed:

A. Verifications activities cover the following:

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

B. Validation activities cover the following:

- Validation of the multifunctional requirements in terms of design.
- Usability testing was performed to demonstrate that VEA Align can be used safely by assessing and mitigating usability risks.
- Validation of the reproducibility and accuracy of clinical parameter outputs.
- Standalone performance assessment of the machine learning algorithm. The testing dataset consisted of 555 patients which demographic characteristics covering the intended use population, including images from EOS (K152788) and EOSedge (K202394) systems. Direct comparison between skeletal landmark locations between the subject VEA Align device and predicate sterEOS Workstation (K172346) met acceptance criteria for algorithm performance.

8 CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device, VEA Align, is substantially equivalent to the legally marketed predicate device in regards to indications for use, intended use, design, technology, and performance.