EOS imaging
% Mathilde Masurel
Design Quality and Regulatory Affairs Specialist
10 rue Mercoeur
Paris, 75011
France

October 24, 2023

Re: K232086
Trade/Device Name: spineEOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 27, 2023
Received: September 27, 2023

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.

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, Ph.D.
Assistant Director
Imaging Software Team
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)*
K232086

Device Name
spineEOS

Indications for Use *(Describe)*
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.

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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1 SUBMITTER

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Date Summary Prepared: October 23, 2023

2 DEVICE

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
Premarket Submission Number: K232086

3 LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Name	Clearance Date
K160407	spineEOS	August 2016

4 DEVICE DESCRIPTION

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

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.

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	Cleared spineEOS (K160407)	Modified spineEOS	Substantially Equivalent?
Indications for Use	Using 3D data and models obtained from sterEOS workstation, spineEOS software is indicated for assisting healthcare professionals in viewing, measuring images as well as in preoperative planning of spine surgeries. The device includes tools for measuring spine anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software online.	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.	Yes, the modified spineEOS has the same intended use as the cleared spineEOS. Specifically, both devices are indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The modified spineEOS has slightly modified indications for use. Specifically, the indications for use statement maintains the basic explanation of the device inputs and available tools. In sum, the same information is provided to the end user; it is simply not organized in the same way. Thus, this change does not raise different questions of safety or effectiveness.
Regulatory Class/Code	Class II LLZ (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	Yes, same.
Device Classification Name	System, image processing, radiological	System, image processing, radiological	Yes, same.
User Population	spineEOS can only be used by a trained user including: • Spine surgeons to define and validate the surgical plan. • Implant distributors to define and save the optional pre-planning.	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.	Yes, similar. The modified spineEOS has EOS staff in addition to the users of cleared spineEOS. This minor change does not affect the safety and effectiveness of the product because EOS staff has the same account right as the implant distributors already considered in the predicate and needs to be properly trained in order to use the product.
Target Population	Patients 7 years or older who need spine surgery. spineEOS is	Patients 7 years or older who need spine surgery. spineEOS is	Yes, same. The modified spineEOS has the same target population as the cleared spineEOS.

Characteristic	Cleared spineEOS (K160407)	Modified spineEOS	Substantially Equivalent?
	recommended in the preoperative planning of spine surgeries for: • Degenerative surgery • Deformative adult spine surgery • Adolescent Idiopathic Scoliosis (AIS) surgery.	recommended in the preoperative planning for spine surgeries for: • Degenerative Spine Surgery • Deformative Spine Surgery • Adolescent Idiopathic Scoliosis (AIS) surgery.	Specifically, both devices are intended for patients 7 years or older who need spine surgery. Modified spineEOS has slightly modified target population statement as compared to the predicate. Specifically, the target population statement maintains the description of degenerative and deformative spine surgery for patients 7 years or older as well as the description of AIS surgery but in a more consistent way. In sum, the same information is provided to the end user; it is simply stated differently. Thus, this minor change does not raise different questions of safety or effectiveness.
Hardware and Software Requirement	**Web Browsers:** • Windows 7/8.1/10: Google Chrome 47, Mozilla Firefox 43, Opera 34; • For Macintosh OS X Yosemite 10.10 et El Capitan 10.11: Google Chrome 47, Mozilla Firefox 43, Opera 34 et Safari 9. **PC Configuration:** Stable internet connection - Dual Core 2.4 GHz processor, 4 GB of RAM and integrated graphics board. **Screen Resolution:** The minimum screen resolution ensuring full display of the	**Web Browsers:** • Windows 10/11: Google Chrome, Mozilla Firefox, Edge • For macOS 12/13: Google Chrome, Mozilla Firefox, Safari **PC Configuration:** Stable internet connection - Dual Core 2.4 GHz processor, 4 GB of RAM and integrated graphics board. **Screen Resolution:** The minimum screen resolution ensuring full display of the planning page is 1920 x 1080 pixels. At resolutions below 1600 x 900, the application prompts the user to toggle	Yes, similar. The differences between modified spineEOS and the predicate take into account the evolution of the web browsers. These minor changes do not affect the safety and effectiveness of the product.

Characteristic	Cleared spineEOS (K160407)	Modified spineEOS	Substantially Equivalent?
	planning page is 1920 x 1080 pixels. At resolutions below 1600 x 900, the application prompts the user to toggle to full screen display to ensure correct visualization.	to full screen display to ensure correct visualization.	
Input Data	• Patient's information • X-rays images • 3D model of the spine	• Patient's information • X-rays images • 3D model of the spine	Yes, same.
Product Workflow	**Model Validation:** allow users to validate or reject the 3D modeling. **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	**Model Validation:** allow users to validate or reject the 3D modeling. **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	Yes, same.
Tools Available for Planning	• Segmental Alignment • Interbody Implant • Osteotomy	• Segmental Alignment • Interbody Implant • Osteotomy • Spondylolisthesis • Rod Curvature Management	Yes, similar. Modified spineEOS is an updated version of the cleared spineEOS. The fundamental tools of modified spineEOS are unchanged from the cleared spineEOS. Both devices have tools for segmental alignment, interbody implant, and osteotomy. Modified spineEOS main difference from the cleared spineEOS is the introduction of the spondylolisthesis tool. This tool operates on the same principle than the existing segmental alignment tool, except that it allows movement of the vertebra on a different axis (translation for the spondylolisthesis tool vs. rotation for the segmental

Characteristic	Cleared spineEOS (K160407)	Modified spineEOS	Substantially Equivalent?
			alignment tool) and the possibility to manage the rod curvature. The introduction of this tool does not affect the device safety and effectiveness.
Software Functionalities / Modalities	Obtains an image and 3D model transferred from other devices	Obtains an image and 3D model transferred from other devices	Yes, same.
	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, same.
	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, same.
	Requires human intervention for interpretation and manipulation of images	Requires human intervention for interpretation and manipulation of images	Yes, same.
Image Manipulation Functions	2D images and 3D model display and basic manipulation (zoom, panning and angles measurements)	2D images and 3D model display and basic manipulation (zoom, panning, distance, and angles measurements)	Yes, same. In modified spineEOS, the possibility of measuring distance directly in the image is based on the same principle as the measurement of angles, already available in the cleared spineEOS. It does not affect the device safety and effectiveness.
Measurement Functions	Distances and Angles	Distances and Angles	Yes, same.
User Interface	Computer	Computer	Yes, same.
Software Environment	Cloud-based software	Cloud-based software	Yes, same.

7 PERFORMANCE DATA

Nonclinical performance testing performed on the subject device, spineEOS, 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 spineEOS can be used safely by assessing and mitigating usability risks.
- Validation of the clinical parameters

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

8 CONCLUSION

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