May 28, 2025

Smart Soft Healthcare AD
Yoana Ivanova
Regulatory Affairs Director
113 General Kolev Str., Primorski District., Office 7.2
Varna, 9002
Bulgaria

Re: K250367
Trade/Device Name: CoLumboX
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 30, 2025
Received: April 30, 2025

Dear Yoana Ivanova:

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,

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)*
K250367

Device Name
CoLumboX

Indications for Use *(Describe)*
CoLumboX is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine radiograph x-ray images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting measurements:
· Feature segmentation;
· Feature measurement;
· Threshold-based labeling of out-of-range measurement; and
· Export of measurement results.
CoLumboX does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and classify features in lumbar x-ray images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, and utilizing CoLumboX output using their medical judgment and discretion.
The device is intended to be used only by hospitals and other medical institutions. Only DICOM x-ray images of patients aged 18 and older are considered to be valid input. CoLumboX does not support DICOM images of patients who are pregnant, or those with post-operative complications, tumors, or infections.

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

1. Submitter

Smart Soft Healthcare AD
Address: 113 General Kolev Str., Primorski District., Office 7.2 Varna 9002, Bulgaria
Phone: +35952919513
Fax: None
Contact Person: Nedelcho Georgiev
Date Prepared: February 10, 2025

2. Device

Name of Device: CoLumboX
Common or Usual Name: CoLumboX
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Product Code: QIH
Regulatory Class: II

3. Predicate Device

1) Predicate device:
Device Name: CoLumbo
Manufacturer: Smart Soft Healthcare AD
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Classification Product Code: QIH
Classification Panel: Radiology
Device Class: Class II
510(k) Number: K241211 cleared August 15, 2024

2) Reference device:
Device Name: Spine CAMP
Manufacturer: Medical Metrics, Inc.
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Classification Product Code: QIH
Classification Panel: Radiology
Device Class: Class II
510(k) Number: K231668 cleared July 7, 2023

4. Device Description

CoLumboX is a medical device (software) for viewing and interpreting radiograph (x-ray) images of the lumbar spine. The software is a quantitative imaging tool that assists radiologists and neuro- and spine surgeons (“users”) to identify and measure lumbar spine features in medical

images. The users then review the out-of-range measurements provided by the software. The measurements are classified using “modifiers” based on rule-based algorithms and thresholds set by each software user and stored in the user’s individualized software settings.

The purpose of CoLumboX is to provide information regarding spondylolisthesis slippage measurements. The software automatically initiates measurements resulting from segmentation of the vertebrae and sacrum. Segmentations serve the purpose of calculating measurements. The device outputs are intended to be a starting point for a clinical workflow and should not be interpreted or used as a diagnosis. The output is an aid to the clinical workflow of measuring patient anatomy and should not be misused as a diagnosis tool.

User-confirmed/defined settings control the software for labelling measurements in an image. The user (not the software) controls the threshold for identifying out-of-range measurements. The software facilitates this process by detecting contours (segmentations) around features of the relevant anatomy and displaying measurements based on these contours. The user maintains control of the process by inspecting the measurements and annotations upon which the measurements are based. The user may also examine other features of the imaging not annotated by the software to form a complete impression and diagnostic judgment of the overall state of disease, disorder, or trauma.

5. Indications for Use

CoLumboX is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine radiograph x-ray images for users’ review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting measurements:

- Feature segmentation;
- Feature measurement;
- Threshold-based labeling of out-of-range measurement; and
- Export of measurement results.

CoLumboX does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and classify features in lumbar x-ray images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, and utilizing CoLumboX output using their medical judgment and discretion.

The device is intended to be used only by hospitals and other medical institutions.

Only DICOM x-ray images of patients aged 18 and older are considered to be valid input. CoLumboX does not support DICOM images of patients who are pregnant, or those with post-operative complications, tumors, or infections.

6. Comparison of the Technological Characteristics with the Predicate Devices

In comparison to the Predicate Device, the Subject Device provides comparable outputs in terms

of segmentation, measurement and labeling. A tabular high-level comparison of the Subject Device, the Predicate Device and the Reference Device is provided as **Table 1** below.

Table 1 – *Comparison of Technological Characteristics with Predicate Device*

	Predicate Device (K241211)	**Reference Device (K231668)**	**Subject Device**	**Remark/ Discussion**
Device Name	CoLumbo	Spine CAMP™ (1.1)	CoLumboX	n/a
Manufacturer	Smart Soft Healthcare	Medical Metrics, Inc.	Smart Soft Healthcare	n/a
Classification Panel	Radiology	Radiology	Radiology	Same
CFR Section	21 CFR 892.2050 (Medical image management and processing system) QIH	21 CFR 892.2050 (Medical image management and processing system) QIH	Proposed: 21 CFR 892.2050 (Medical image management and processing system) QIH	Same
Device Class	Class II	Class II	Class II	Same
Intended Use	Intended to assist the radiologist, spine- and neuro-surgeon in performing routine evaluations of lumbar spine MRI exams and producing a report of findings summarizing the results of the evaluation.	Spine CAMP™ is a fully-automated image processing software device. It is designed to be used with X-ray images and is intended to aid medical professionals in the measurement and assessment of spinal parameters. Spine CAMP™ is capable of calculating distances, angles, linear displacements, angular displacements, and mathematical combinations of these metrics to characterize the morphology, alignment, and motion of the spine. These analysis results are presented in the form of reports, annotated images, and visualizations of intervertebral motion to support their interpretation.	Intended to assist the radiologist, spine- and neuro-surgeon in performing routine evaluations of lumbar spine x-ray images.	Similar
Indications for Use	CoLumbo is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following	Spine CAMP™ is a fully-automated software that analyzes Xray images of the spine to produce reports that contain static and/or motion metrics. Spine CAMP™ can be used to obtain metrics from sagittal plane radiographs of the lumbar and/or cervical spine and it can be used to	CoLumboX is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine x-ray images for users' review, analysis, and interpretation. It provides the following functionality to assist users	Similar

	functionality to assist users in visualizing, measuring and documenting out-of-range measurements: • Feature segmentation; • Feature measurement; • Threshold-based labeling of out-of-range measurement; and • Export of measurement results to a written report for user's review, revise and approval. CoLumbo does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and classify features in lumbar MR images and compile a report. The user is responsible for confirming/modifying settings, reviewing and verifying the software-generated measurements, inspecting out-of-range measurements, and approving draft report content using their medical judgment and discretion. The device is intended to be used only by hospitals and other medical institutions. Only DICOM images of MRI acquired from lumbar spine exams of patients aged 18 and above are considered to be valid input. CoLumbo does not support DICOM images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operative complications, tumors, infections.	visualize intervertebral motion via an image registration method referred to as "stabilization." The radiographic metrics can be used to characterize and assess spinal health in accordance with established guidance. For example, common clinical uses include assessing spinal stability, alignment, degeneration, fusion, motion preservation, and implant performance. The metrics produced by Spine CAMP™ are intended to be used to support qualified and licensed professional healthcare practitioners in clinical decision-making for skeletally mature patients of age 18 and above.	in visualizing, measuring and documenting measurements: • Feature segmentation; • Feature measurement; • Threshold-based labeling of out-of-range measurement; and • Export of measurement results. CoLumboX does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and classify features in lumbar x-ray images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, and utilizing CoLumboX output- using their medical judgment and discretion. The device is intended to be used only by hospitals and other medical institutions. Only DICOM x-ray images of patients aged 18 and older are considered to be valid input. CoLumboX does not support DICOM images of patients who are pregnant or those with post-operative complications, tumors, or infections.	
Intended User	Radiologist & neuro- and spine-surgeons	Trained professionals	Radiologist & neuro- and spine-surgeons	Same
Intended Patient Population	The intended patient population is not subject to any restrictions. Automation support requires images of patients of 18 years and older, not	Skeletally mature patients of age 18 and above	Skeletally mature patients of age 18 and older that are not pregnant and do not have post-operative complications, tumors, infections.	Highly Similar

	pregnant, without post-operative complications, tumors, infections.			
Supported Body Part	Lumbar spine	Lumbar and/or cervical spine	Lumbar spine	Same
Threshold-Based Out-of-Range Measurements	Yes	Yes	Yes	Same
Supported Modality	MR	X-ray	X-ray	Same with reference device

The Subject Device is substantially equivalent in comparison to the Predicate Device. The information regarding the Subject Device does not raise new questions about safety and effectiveness, and demonstrates that CoLumboX is at least as safe and effective as its predicate device.

7. Performance Data

Smart Soft Healthcare has performed software design verification testing and has sponsored external software performance assessment study with clinical data. The performance data demonstrates continued conformance for medical devices containing software.

Smart Soft Healthcare conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient. The vulnerability assessment and penetration testing demonstrate satisfactory security performance with no critical and high-risk vulnerabilities.

Software Performance Validation on Clinical Data

To validate the CoLumboX software, ver. 2, from a clinical perspective, a clinical data-based software performance assessment study was conducted in the U.S. The software performance assessment study of CoLumboX included 100 image studies for 100 patients of different gender, ages and racial groups. The performance assessment study compared the CoLumboX software outputs, and the output of a physician using and physician not using CoLumboX to the ground truth defined by 3 radiologists on segmentations and measurements.

8. Conclusions

The CoLumboX software demonstrates substantial equivalence to the predicate device. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between subject and predicate device in indications do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labeled.

The software verification and validation testing data, including the standalone software performance assessment study data, supports the safety of the devices and demonstrates that the

CoLumboX software performs as intended in the specified use conditions.

Therefore, the CoLumboX software is substantially equivalent.