April 1, 2026

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

Re: K254015
Trade/Device Name: CoLumbo C-Spine
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 4, 2026
Received: March 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Catherine Olguin

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)*
K254015

Device Name
CoLumbo C-Spine

Indications for Use *(Describe)*
CoLumbo C-Spine is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM cervical spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting out-of-range measurements:

- Segmentation of the vertebrae (C3-C7) and disks (C2C3-C7T1);
- Measurements based on the segmentation;
- Threshold-based labeling of out-of-range measurement; and
- Export of measurement results.

CoLumbo C-Spine does not produce or recommend any type of medical diagnosis or treatment. The device outputs are intended to be a starting point for a clinical workflow and should not be interpreted or used as a diagnosis. Instead, CoLumbo C-Spine simply helps users to more easily identify and classify features in cervical MR images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, utilizing CoLumbo C-Spine's output using their medical judgment and discretion.
The device is intended to be used only by hospitals and other medical institutions.
Only DICOM MR images of the spine of patients aged 22 and above with adequate visualization of C2–C7 are considered to be valid input. Performance has not been established in the presence of vertebral enumeration variants that may interfere with reliable vertebral counting, including true cervical ribs, hemivertebrae, congenital or acquired vertebral fusion, for images acquired with contrast media, for cases involving tumors, infections, post-operative changes, or vertebral fusion, or for examinations in which the C2 vertebra is not adequately visualized.

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.

K254015

510(k) Summary

1. Submitter

Smart Soft Healthcare AD
Address: 113 General Kolev Str., Primorski District., Office 7.2 Varna 9002, Bulgaria
Phone: +359 52 919 513
Fax: None
Contact Person: Yoana Ivanova
Date Prepared: April 1, 2026

2. Subject Device

Name of Device: CoLumbo C-Spine
Common or Usual Name: Automated Radiological Image Processing Software
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Product Code: QIH
Regulatory Class: II

3. 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

4. Device Description

CoLumbo C-Spine is a medical device (software) for assisting in the viewing and interpretation of magnetic resonance imaging (MRI) of the cervical spine. The software is an assistive tool that helps users to identify and measure c-spine features in medical images. The segmentation and measurements provided by the software are classified based on rule-based algorithms, and thresholds set by each software user and stored in the user's individualized software settings. The purpose of CoLumbo C-Spine is to provide information regarding different c-spine measurements. The software automatically initiates measurements resulting from segmentation of the vertebrae (C3-C7) and disks (C2C3-C7T1). Segmentations serve the purpose of calculating measurements. User-defined/confirmed settings control the software per individual user's preference for annotating features in an image that may have out-of-range 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. CoLumbo C-Spine 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 c-spine MR images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, and utilizing CoLumbo C-Spine output using their medical judgment and discretion.

5. Indications for Use

CoLumbo C-Spine is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM cervical spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting out-of-range measurements:

- Segmentation of the vertebrae (C3-C7) and disks (C2C3-C7T1);
- Measurements based on the segmentation;
- Threshold-based labeling of out-of-range measurement; and
- Export of measurement results.

CoLumbo C-Spine does not produce or recommend any type of medical diagnosis or treatment. The device outputs are intended to be a starting point for a clinical workflow and should not be interpreted or used as a diagnosis. Instead, CoLumbo C-Spine simply helps users to more easily identify and classify features in cervical MR images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, utilizing CoLumbo C-Spine's output using their medical judgment and discretion.

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

Only DICOM MR images of the spine of patients aged 22 and above with adequate visualization of C2–C7 are considered to be valid input. Performance has not been established in the presence of vertebral enumeration variants that may interfere with reliable vertebral counting, including true cervical ribs, hemivertebrae, congenital or acquired vertebral fusion, for images acquired with contrast media, for cases involving tumors, infections, post-operative changes, or vertebral fusion, or for examinations in which the C2 vertebra is not adequately visualized.

6. Comparison of the Technological Characteristics with the Predicate Device

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 and the Predicate Device is provided as **Table 1** below.

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

	Predicate Device (K241211)	**Subject Device**	**Remark/ Discussion**
Device Name	CoLumbo	CoLumbo C-Spine	n/a

Manufacturer	Smart Soft Healthcare	Smart Soft Healthcare	n/a
Classification Panel	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	Same
Device Class	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.	Intended to assist the radiologist, spine- and neuro-surgeon in performing routine evaluations of cervical spine MR 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 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	CoLumbo C-Spine is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM cervical spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting out-of-range measurements: ● Segmentation of the vertebrae (C3-C7) and disks (C2C3-C7T1); ● Measurements based on the segmentation; ● Threshold-based labeling of out-of-range measurement; and ● Export of measurement results. CoLumbo C-Spine does not produce or recommend any type of medical diagnosis or treatment. The device outputs are intended to be a starting point for a clinical workflow and should not be interpreted or used as a diagnosis. Instead, CoLumbo C-Spine simply helps users to more easily identify and classify features in cervical MR images and potentially compile a report. The user is responsible for confirming/modifying settings, reviewing the software-generated measurements, utilizing CoLumbo C-Spine's output using their medical judgment and discretion. The device is intended to be used only by hospitals and other medical institutions.	Similar

	images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operative complications, tumors, infections.	Only DICOM MR images of the spine of patients aged 22 and above with adequate visualization of C2–C7 are considered to be valid input. Performance has not been established in the presence of vertebral enumeration variants that may interfere with reliable vertebral counting, including true cervical ribs, hemivertebrae, congenital or acquired vertebral fusion, for images acquired with contrast media, for cases involving tumors, infections, post-operative changes, or vertebral fusion, or for examinations in which the C2 vertebra is not adequately visualized.	
Intended User	Radiologist & neuro- and spine-surgeons	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 pregnant, without post-operative complications, tumors, infections.	Skeletally mature patients of age 22 and older that are not pregnant and do not have fusions, post-operative complications, tumors, infections.	Highly Similar
Supported Body Part	Lumbar spine	Cervical spine	Similar – different parts of the spine
Threshold-Based Out-of-Range Measurements	Yes	Yes	Same
Supported Modality	MR	MR	Same

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 CoLumbo C-Spine is at least as safe and effective as its predicate device CoLumbo.

7. Performance Data

Smart Soft Healthcare has performed software design verification testing and has sponsored external software performance assessment study. 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

To validate the CoLumbo C-Spine software from a clinical perspective, a software performance

assessment study was conducted in the U.S. The software performance assessment study included 95 MRI c-spine studies for 95 patients of different gender, ages and racial groups. The performance assessment study compared the CoLumbo C-Spine software outputs to the ground truth defined by 4 radiologists on segmentations and measurements.

Measurement	MAE	95% CI
Vertebral body height	0.72 mm	(0.56, **0.88 mm**)
Disk height	0.90 mm	(0.76, **1.05 mm**)
Disk material outside of the intervertebral space AP size	0.72 mm	(0.52, **0.92 mm**)
Focal disk material outside of the intervertebral space AP-size	1.29 mm	(0.94, **1.63 mm**)

Tissue Segmentation	MDC	95% CI
Vertebral body (sagittal)	0.90	(0.86, 0.93)
Disk (sagittal)	0.84	(0.81, 0.87)
Disk material outside of the intervertebral space (sagittal)	0.70	(0.68, 0.73)
Focal disk material outside of the intervertebral space (axial)	0.68	(0.64, 0.72)

8. Conclusions

The CoLumbo C-Spine software is as safe and effective as its 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 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 CoLumbo C-Spine software performs as intended in the specified use conditions.