August 15, 2024

Smart Soft Healthcare
Nedelcho Georgiev
CEO
113 Gen. Kolev str, suite 7.2
Varna, 9002
Bulgaria

Re: K241211
Trade/Device Name: CoLumbo
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 16, 2024
Received: July 16, 2024

Dear Nedelcho Georgiev:

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.

Submission Number *(if known)*

K241211

Device Name

CoLumbo

Indications for Use *(Describe)*

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 images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, tumors, 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.

K241211

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: June 25, 2024

2. Device

Name of Device: CoLumbo
Common or Usual Name: CoLumbo ver.3
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: K220497 cleared June 23, 2022

4. Device Description

CoLumbo is a medical device (software) for viewing and interpreting magnetic resonance imaging (MRI) 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 and record their observations in a report. The users then confirm whether the out-of-range measurements represent any true abnormality versus a spurious finding, such as an artifact or normal variation of the anatomy. The segmentation and 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 user also identifies and classifies any other observations that the software may not annotate.

The purpose of CoLumbo is to provide information regarding common spine measurements confirmed by the user and the pre-determined thresholds confirmed or defined by the user. Every feature annotated by the software, based on the user-defined settings, must be reviewed and

affirmed by the user before the measurements of these features can be stored and reported. The software semi-automatically initiates adjustable measurements resulting from segmentation. Segmentations are not intended to be a final output but serve the purpose of visualization and 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 user is responsible for confirming segmentation and all measurement outputs. 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 sensitivity of the software for labelling measurements in an image. The user (not the software) controls the threshold for identifying out-of-range measurements, and, in every case once an out-of-range measurement is identified, the user must confirm or reject its presence. The software facilitates this process by annotating or drawing 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 segmentation, 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

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 images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, tumors, 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 and the Predicate Device is provided as **Table 1** below.

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

	Predicate Device CoLumbo Version 2 **(K193290)**	**Subject Device** CoLumbo Version 3	**Remark/Discussion**
Regulation	892.2050	892.2050	Same
Product Code	**QIH**	**QIH**	Same
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-	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	Highly similar Indications for use are the same with the list of contraindications changed.

	Predicate Device CoLumbo Version 2 **(K193290)**	**Subject Device** CoLumbo Version 3	**Remark/Discussion**
	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-operational complications, scoliosis, tumors, infections, fractures.	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-operational complications, tumors, infections.	
Intended User	Radiologist and neuro- and spine-surgeons	Radiologist and 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-operational complications, scoliosis, tumors, infections, fractures.	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-operational complications, tumors, infections.	Highly similar
Supported Body Part	Lumbar Spine	Lumbar Spine	Same
Segmentation	Yes Segmentation and quantitative analysis	Yes Segmentation and quantitative analysis	Same
Measurement	Yes Quantitative comparison of structure with normative data or user-set thresholds	Yes Quantitative comparison of structure with normative data or user-set thresholds	Same

	Predicate Device CoLumbo Version 2 **(K193290)**	**Subject Device** CoLumbo Version 3	**Remark/Discussion**
Threshold-Based Out-of-Range Measurements	Yes Quantitative comparison of structure with normative data or user-set thresholds	Yes Quantitative comparison of structure with normative data or user-set thresholds	Same
Reporting	Yes	Yes	Same
SaMD	Yes	Yes	Same
Algorithm	Deep Convolutional Image-to-Image Neural Network	Deep Convolutional Image-to-Image Neural Network	Same
Supported Modality	MR	MR	Same
Supported Measurements	• Focal disk material outside VB projection and its migration – descending and ascending; • Disk outside VB projection; • Dural sac cross-sectional area; • Nerve root deviation; • Vertebral body height; • Disk height; • Lordotic angle; • Spondylolisthesis slippage;	• Focal disk material outside VB projection; • Descending (caudal) and ascending (cranial) disk material outside of the intervertebral space; • Disk outside VB projection; • Dural sac cross-sectional area; • Nerve root deviation; • Vertebral body height; • Disk height; • Lordotic angle; • Spondylolisthesis slippage; • Angle of lateral spinal curvature; • Facet joint diameter; • Posterior epidural fat size; • Muscle fat infiltration percentage; • Foramen diameter; • Lateral recess diameter; • Dural sac anterior-posterior diameter; • Spinal canal diameter; • Disk Material Outside of Endplate Margins Size;	Highly similar The Subject Device supports several more measurements.

	Predicate Device CoLumbo Version 2 **(K193290)**	**Subject Device** CoLumbo Version 3	**Remark/Discussion**
		• Ligament Flavum Thickness; • Vertebral Body Zone with Changed Intensity Size. • Vertebral Body Width Difference AP Size.	

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 is at least as safe and effective as its previously legally marketed version.

7. Performance Data

7.1. Biocompatibility Testing

Not applicable.

7.2. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable.

7.3. Animal Study

Not applicable.

7.4. Voluntary Conformance Standards

CoLumbo has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrated that CoLumbo complies with the following voluntary FDA recognized Consensus Standards listed in **Table 2** below.

Table 2 - *Voluntary Conformance Standards*

Recognition #	**Standard**
13-79	IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes — Amendment 1
13-97	IEC 82304-1:2016 Health software — Part 1: General requirements for product safety
5-125	ISO 14971:2019 Medical devices — Application of risk management to medical devices
5-129	IEC 62366-1:2015+AMD1:2020 Medical devices — Part 1: Application of usability engineering to medical devices

5-135	ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer

7.5. Nonclinical Tests

Smart Soft Healthcare has performed software design verification testing and has sponsored external standalone 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 demonstrates satisfactory security performance with no critical and high risk vulnerabilities.

Standalone Software Performance Validation

To validate the CoLumbo software, ver. 3, from a clinical perspective, a clinical data based standalone software performance assessment study was conducted in the U.S. The standalone software performance assessment study of CoLumbo included 100 MR image studies for 100 patients of different ages and racial groups. The standalone software performance assessment study compared the CoLumbo software outputs without any editing by a radiologist to the ground truth defined by 3 radiologists on segmentations and measurements.

7.6. Clinical Validation Study

No human clinical study was conducted to support the pre-market clearance.

8. Conclusions

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

Therefore, the CoLumbo software is substantially equivalent.