Smart Soft Healthcare AD
℅ Yu Zhao
Strategy Advisor
LightSource Research LLC
2108 N St., Suite N
SACRAMENTO CA 95816

June 23, 2022

Re: K220497
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: May 31, 2022
Received: June 1, 2022

Dear Yu Zhao:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220497

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, scoliosis, tumors, infections, fractures.

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
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Varna 9002, Bulgaria
Phone: +35952919513
Fax: None
Contact Person: Nedelcho Georgiev
Date Prepared: February 5, 2022

2. Device

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

3. Predicate Devices

Predicate Device:

Device Name: AI-Rad Companion Brain MR
Manufacturer: Siemens Healthcare GmbH
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Secondary Classification Name: Magnetic resonance diagnostic device
Classification Product Code: LLZ
Subsequent Product Code: LNH
Classification Panel: Radiology
Device Class: Class II
510(k) Number: K193290 cleared July 5, 2019

Reference Device 1:

Device Name: AI-Rad Companion (Cardiovascular)
Manufacturer: Siemens Medical Solutions USA, Inc.
Classification Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Classification Product Code: JAK
Subsequent Product Code: LLZ
Classification Panel: Radiology
Device Class: Class II

510(k) Number: K183268 cleared September 10, 2019

Reference Device 2:

Device Name: AI-Rad Companion (Musculoskeletal)

Manufacturer: Siemens Medical Solutions USA, Inc.

Classification Name: Computed tomography x-ray system

Regulation Number: 21 CFR 892.1750

Classification Product Code: JAK

Classification Panel: Radiology

Device Class: Class II

510(k) Number: K193267 cleared March 16, 2020

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 provides 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 radiologist before the measurements of these features can be stored and reported. The software initiates adjustable measurements resulting from semi-automatic segmentation. If the user rejects a measurement the corresponding segmentation is rejected too. 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, scoliosis, tumors, infections, fractures.

6. Comparison of the Technological Characteristics with the Predicate Devices

In comparison to the Predicate Device and the Reference Devices, 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 Devices is provided as **Table 8.1** below.

Table 8.1 – *Comparison of Technological Characteristics with Predicate/Reference Devices*

	Predicate Device - AI-Rad Companion Brain MR **(K193290)**	**Reference Device 1 -** AI-Rad Companion (Cardiovascular) **(K183268)**	**Reference Device 2 -** AI-Rad Companion (Musculoskeletal) **(K193267)**	**Subject Device** CoLumbo	**Remark/Discussion**
Intended User	Radiologist	Radiologists & Physicians from emergency medicine, specialty care, urgent care, and general practice	Radiologists & Physicians from emergency medicine, specialty care, urgent care, and general practice	Radiologist and neuro- and spine-surgeons	Highly similar
Intended Patient Population	The intended patient target group consists of patients of age 2 years or higher. In this age range the brain segmentation algorithm works properly.	The intended patient population is not subject to any restrictions. Automation support requires images of patients of 22 years and older.	The intended patient population is not subject to any restrictions. Automation support requires images of patients of 22 years and older.	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.	Similar
Supported Body Part	Brain	Thorax	Thorax (including thoracic spine)	Lumbar Spine	Similar to Reference Devices; Different from Primary Device
Segmentation	Yes Segmentation and quantitative analysis	Yes Segmentation and quantitative analysis	Yes Segmentation of vertebras	Yes Segmentation and quantitative analysis	Same
Measurement	Yes Quantitative comparison of structure with normative data or user-set thresholds	Yes Volume measurement of the heart, total calcium volume in the coronary arteries,	Yes Measure Hounsfield values within the vertebras	Yes Quantitative comparison of structure with normative data or user-set thresholds	Same

	Predicate Device - AI-Rad Companion Brain MR **(K193290)**	**Reference Device 1 -** AI-Rad Companion (Cardiovascular) **(K183268)**	**Reference Device 2 -** AI-Rad Companion (Musculoskeletal) **(K193267)**	**Subject Device** CoLumbo	**Remark/Discussion**
		maximum diameters of the aorta at typical landmarks			
Threshold-Based Out-of-Range Measurements	Yes Quantitative comparison of structure with normative data or user-set thresholds	Yes Threshold-based highlighting of findings. Classify each finding (e.g., enlarged diameters) by comparing measurements against user-set thresholds	Yes Labeling of vertebras based on the individual heights of the vertebras and whether they critically differ from their direct neighbors	Yes Quantitative comparison of structure with normative data or user-set thresholds	Similar
Reporting	Yes Exportation of results with the findings for further reporting	Yes Exportation of results with the findings for further reporting	Yes Exportation of results with the findings for further reporting	Yes Exportation of results with the measurements for further reporting	Same None of the reports are to be used as final reports. Trained radiologist or neuro- and spine-surgeons need to review, edit and approve the final report
SaMD	Yes	Yes	Yes	Yes	Same
Algorithm	(no information)	3D Deep Image-to-Image Network	3D Deep Image-to-Image Network	Deep Convolutional Image-to-Image Neural Network	Similar
Supported Modality	MR	CT	CT	MR	Same as Primary Predicate Device 1; Similar to Reference Devices

The Subject Device is substantially equivalent in comparison to the Predicate/Reference Devices. The information regarding the Subject Device do not raise new questions about safety and effectiveness and demonstrate that CoLumbo is at least as safe and effective as the legally marketed devices.

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 8.2** below.

Table 8.2 - *Voluntary Conformance Standards*

Recognition #	Standard
13-79	IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes — Amendment 1
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
5-117	ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
12-300	NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set

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 with special controls for medical devices containing software.

Software documentation for a Moderate Level of Concern software, per FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005, were provided. Smart Soft Healthcare has conducted software verification and validation, in accordance with the FDA guidance, *General Principles of Software Validation; Final Guidance for*

Industry and FDA Staff, issued on January 11, 2002. All software requirements and risk analysis have been successfully verified and traced.

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.

In addition to the human factors validation, Smart Soft Healthcare conducted a standalone software performance study in the U.S. to validate clinical performance of the CoLumbo software.

The nonclinical test data demonstrated conformance with special controls and substantial equivalence to predicate devices' performance.

Standalone Software Performance Validation

To validate the CoLumbo software 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 101 MR image studies for 101 patients of different ages and racial groups, collected from seven (7) sites across the U.S. 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.

Study Subjects:

	Number of Subjects	Percent of Total
Total Number of Subjects	101	100%
Gender – Male	53	52.5%
Gender - Female	48	47.5%
Age – 18 through 21	3	3.0%
Age – 22 through 50	74	73.3%
Age – 51 and above	24	23.8%
Racial – Caucasian	83	82.2%
Racial – Black/African American	9	8.9%
Racial – Hispanic	3	3.0%
Racial – American Indian	3	3.0%
Racial – Others	3	3.0%

Imaging Systems:

The 101 study images were acquired on MRI imaging systems made by five (5) manufacturers. All scans were conducted using the protocols standard for the investigational center, containing at least one axial and sagittal T2 series.

Manufacturer	Number of MRI Exams Collected	Percent of Total
Toshiba (1.5T & 3.0T)	65	64.4%
Siemens (1.5T)	17	16.8%
Philips (1.5T)	1	1.0%
Hitachi (1.5T)	1	1.0%
GE (1.5T)	17	16.8%

Total	**101**	**100%**

Ground Truth:

The ground truths for segmentations and measurements were independently established by three (3) U.S. radiologists without using the CoLumbo software. Each radiologist used a specialized pixel labeling tool to independently label the pixels of the tissues at the predetermined levels of the preselected axial and sagittal slices. The per-pixel majority opinion of the three (3) radiologists established the ground truth for each segmented tissue. Similarly, each radiologist used a commercial software tool to produce a standard set of areal, angular and linear measurements. The ground truth measurements were established by taking the median of three radiologists' measurements.

Acceptance Criteria and Results:

Primary endpoint (measurement accuracy):

- the maximum Mean Absolute Error as defined as the upper limit of the 95% confidence interval for MAE is below a predetermined allowable error limit (MAE_{Limit}) for each measurement listed.

Primary end point results: all primary endpoints were met.

Measurement	Mean Absolute Error (MAE)	95% Confidence Interval (CI)	MAE_{Limit}
Dural Sac Area (Axial)	14.8 mm^2	12.4 - **17.3 mm^2**	**20 mm^2**
Lordotic Angle (Sagittal)	2.6°	1.9 - **3.3°**	**6°**
Listhesis/AP Slip (Sagittal)	0.9 mm	0.8 - **1.1 mm**	**2 mm**

Secondary endpoint (measurement and segmentation accuracy):

- the maximum Mean Absolute Error, defined as the upper limit of the 95% confidence interval for MAE, is below a predetermined allowable error limit (MAE_{Limit}) for each measurement listed.
- the minimum Mean Dice Coefficient, defined as the lower limit of the 95% confidence interval for MDC, is above a predetermined allowable limit (MDC_{Limit}) for each segmentation listed.

Secondary endpoint results: all secondary endpoints on measurement and segmentation were met.

Measurement	Mean Absolute Error (MAE)	95% Confidence Interval (CI)	MAE_{Limit}
Disc Material Outside IV Space (Axial)	1.4 mm	1.1 - **1.6** mm	**2** mm
Disc Material Migration (Sagittal)	1.2 mm	1.0 - **1.4** mm	**2** mm
Disc Material Bulge (Axial)	1.0 mm	0.8 - **1.2** mm	**2** mm
Dural Sac AP Diameter (Axial)	1.0 mm	0.8 - **1.1** mm	**2** mm
Intervertebral Angle (Sagittal)	2.2°	1.9 - **2.5**°	**6**°
Anterior VB Height (Sagittal)	0.8 mm	0.7 - **0.9** mm	**2** mm
Middle VB Height	0.8 mm	0.7 - **0.9** mm	**2** mm

(Sagittal)			
Posterior VB Height (Sagittal)	1.0 mm	0.9 – **1.2** mm	**2** mm
Anterior Disc Height (Sagittal)	1.0 mm	0.7 – **1.0** mm	**2** mm
Middle Disc Height (Sagittal)	0.8 mm	0.7 – **0.9** mm	**2** mm
Posterior Disc Height (Sagittal)	1.1 mm	1.0 – **1.2** mm	**2** mm

Tissue Segmentation	**Mean Dice Coefficient (MDC)**	**95% Confidence Interval (CI)**	**MDC_{Limit}**
Disc/Vertebral Body (Axial)	0.97	**0.96** - 0.97	**0.8**
Vertebral Arch and Adjacent Ligaments (Axial)	0.87	**0.86** - 0.88	**0.8**
Dural Sac (Axial)	0.92	**0.92** - 0.93	**0.8**
Nerve Roots (Axial)	0.75	**0.72** - 0.78	**0.6**
Disc Material Outside Intervertebral Space (Axial)	0.76	**0.72** - 0.80	**0.6**
Disc (Sagittal)	0.93	**0.93** - 0.94	**0.8**
Vertebral Body (Sagittal)	0.95	**0.94** - 0.95	**0.8**
Sacrum S1 (Sagittal)	0.93	**0.92** - 0.94	**0.8**
Disc Mat. Outside IV Space and/or Bulging Part (Sagittal)	0.69	**0.66** - 0.72	**0.6**

CoLumbo was shown to produce measurements and segmentations accurate to within a prospectively-defined margin of error around the Ground Truth. This accuracy was preserved for all critical subgroups, including MRI scanner manufacturer, race, sex, and patient age.

MAE for software measurements and MDC for software segmentations by MRI scanner manufacturer:

Measurement Type	**MAE**			**95% Confidence Intervals**			**MAE_{Limit}**
	Toshiba	**Siemens**	**GE**	**Toshiba**	**Siemens**	**GE**	
Angular Measurements	2.0°	2.3°	3.6°	1.8 - **2.3**°	1.6° - **3.0**°	1.7° - **5.6**°	**6**°
Linear Measurements	0.9 mm	0.9 mm	1.0 mm	0.9 - **1.0** mm	0.8 - **1.0** mm	0.9 - **1.1** mm	**2** mm
Segmentation Type	**MDC**			**95% Confidence Intervals**			**MDC_{Limit}**
	Toshiba	**Siemens**	**GE**	**Toshiba**	**Siemens**	**GE**	
Compression-related Tissue Segmentations	0.73	0.69	0.76	**0.71** - 0.76	**0.63** - 0.75	**0.71** - 0.81	**0.6**
Other Tissue Segmentations	0.93	0.93	0.94	**0.92** - 0.93	**0.92** - 0.93	**0.93** - 0.95	**0.8**

MAE for software measurements and MDC for software segmentations by race:

Measurement Type	**MAE**	**MAE**	**95% Confidence Intervals**	**MAE_{Limit}**

	White	Non-White	White	Non-White	
Angular Measurements	2.4°	2.3°	1.9 - **2.9**°	1.7 - **2.9**°	**6**°
Linear Measurements	0.9 mm	1.1 mm	0.9 - **1.0** mm	1.0 - **1.2** mm	**2** mm
Segmentation Type	**MDC White**	**MDC Non-White**	**95% Confidence Intervals**		**MDC_{Limit}**
			White	**Non-White**	
Compression-related Tissue Segmentations	0.73	0.72	**0.71** - 0.75	**0.67** - 0.78	**0.6**
Other Tissue Segmentations	0.93	0.93	**0.925** - 0.933	**0.92** - 0.94	**0.8**

MAE for software measurements and MDC for software segmentations by gender:

Measurement Type	**MAE Male**	**MAE Female**	**95% Confidence Intervals**		**MAE_{Limit}**
			Male	**Female**	
Angular Measurements	2.3°	2.4°	1.7 - **3.1**°	2.1 - **2.7**°	**6**°
Linear Measurements	0.8 mm	0.9 mm	0.9 - **1.0** mm	0.9 - **1.0** mm	**2** mm
Segmentation Type	**MDC Male**	**MDC Female**	**95% Confidence Intervals**		**MDC_{Limit}**
			Male	**Female**	
Compression-related Tissue Segmentations	0.75	0.71	**0.72** - 0.78	**0.68** - 0.74	**0.6**
Other Tissue Segmentations	0.93	0.93	**0.92** - 0.94	**0.92** - 0.93	**0.8**

The following tables represent MAE and DICE statistics for each of the age groups in the aforementioned table.

Tissue Segmentation Type or Measurement	**Acceptance Criteria**	**Between 18 and 21 years old**	**Standard Deviation**	**Number of Samples**	**Confidence Interval**
Angle-based Measurements	6°	1.14°	1.41°	6	(0.48 – 1.81°)
Linear Measurements	2 mm	0.83 mm	1.06mm	36	(0.60 – 1.05mm)
Compression-related Tissue Segmentations	0.6	0.76	0.087	7	(0.70 – 0.83)
Other Tissue Segmentations	0.8	0.92	0.039	18	(0.91 – 0.94)

Tissue Segmentation Type or Measurement	**Acceptance Criteria**	**Between 22 and 50 years old**	**Confidence Interval**
Angle-based Measurements	6°	2.43°	(1.94 – 2.93°)
Linear Measurements	2 mm	0.95 mm	(0.90 – 1.00mm)
Compression-related Tissue Segmentations	0.6	0.73	(0.71 – 0.76)
Other Tissue Segmentations	0.8	0.93	(0.926 – 0.934)

Tissue Segmentation Type or Measurement	Acceptance Criteria	51 years old and above	Confidence Interval
Angle-based Measurements	6°	2.09°	(1.63 – 2.56°)
Linear Measurements	2 mm	0.97 mm	(0.87 – 1.06mm)
Compression-related Tissue Segmentations	0.6	0.72	(0.68 – 0.76)
Other Tissue Segmentations	0.8	0.93	(0.92 – 0.93)

Training, Testing and Validation Data Independence:

The CoLumbo software machine learning algorithm training and testing data used during the algorithm development, as well as validation data used in the U.S. standalone software performance assessment study were all independent data sets.

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, support the safety of the devices and demonstrate that the CoLumbo software performs as intended in the specified use conditions.

Therefore, the CoLumbo software is substantially equivalent.