



June 29, 2026

Agada Medical, Ltd.
% Clay Anselmo
Principal Consultant
Shriner & Associates, Inc.
429 Whitepine Creek Rd.
Trout Creek, MT 59874

Re: K253628

Trade/Device Name: Auto-Seg (SO-0012), Spine Auto-Seg (SO-0012)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 14, 2025
Received: June 1, 2026

Dear Clay Anselmo:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. A large, faint, light blue "FDA" watermark is visible in the background behind the signature.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253628

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Please provide the device trade name(s).

?

AUTO-SEG (SO-0012),
SPINE AUTO-SEG (SO-0012)

Please provide your Indications for Use below.

?

The AGADA SPINE Auto-Seg device is image processing software intended to provide qualitative information from analysis of previously acquired Computed Tomography (CT) DICOM images. The outputs of the software analysis are to be used to support spine surgeons in assessment of musculoskeletal diseases and surgical planning for adults 18 years of age and older. Product functions include; segmentation of thoracic and lumbar vertebrae and pelvis, and labelling of vertebra and pelvis objects. The Auto-Seg device does not provide diagnosis nor recommend treatment and is to be used only as supporting information in clinical decision making.

The device is not intended for use with patients with spinal or pelvic implants.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary – K253628

Introduction:

This document contains the 510(k) Summary for the Agada Medical - Auto-Seg device. The content of this summary is based on the requirements set forth in 21 CFR 807.92(c).

Submitter Information:

Applicant / Manufacturer Name and Address	Agada Medical Ltd. Agada Medical Ltd. 18 Haroshet St. Ramat-Hasharon, Israel 4702519
510(k) Submitter / Preparer	Clay Anselmo Principal Quality and Regulatory Consultant Shriner & Associates, Inc. 429 Whitepine Creek Road Trout Creek, MT 59874 clay.anselmo@shrinerandassociates.com
510(k) Contact Person	Clay Anselmo Principal Quality and Regulatory Consultant Shriner & Associates, Inc. 429 Whitepine Creek Road Trout Creek, MT 59874 clay.anselmo@shrinerandassociates.com
Date prepared	November 14, 2025

Device Identification

Trade names	Auto-Seg (SO-0012), Spine Auto-Seg (SO-0012)
Common name	Automated radiological image segmentation software
Classification name	Medical Image Management and Processing System
Regulation Number	21 CFR Part 892.2050
Classification	Class II
Product Code	Primary: QIH

Predicate Device

Trade names:	Aprevo Digital Segmentation
510(k) number:	K231955

Reference Device

Trade names:	Formus Hip
510(k) number:	K213272

Device Description:

The Auto-Seg device is a software only (SaMD) image processing system that utilizes CT images of the spine and pelvis in DICOM format as input. The device contains four, non-adaptive machine learning models, one model in the pelvis segmentation algorithm and three models in the spine segmentation algorithm. These algorithms produce three dimensional segmentations of spine and pelvis objects. The device also labels the spine and pelvis objects in the output files.

The device runs on a standard personal computer with a graphics processor with pre-defined minimum specifications that are verified by the software during installation and as built-in self-tests.

The device is intended to be used in an office environment, by spinal surgeons on adult patients 18 years of age or older.

The device employs a simple graphical user interface that navigates the user through a single work-flow process that allows the user to upload a single-patient CT study with multiple series solely from an encrypted USB drive. Once uploaded, the software automatically identifies spine and pelvis objects, then performs segmentation using one or both of the algorithms depending on the objects present in the image.

Once segmented, the user is asked to identify the most caudal vertebra in the segmented output, the software then utilizes this information to label the remaining vertebra with confirmation by the user. Pelvis objects are labeled automatically without input from the user.

The output of the segmentation and labeling processes are then exported to the encrypted USB drive for further viewing, analysis and surgical planning purposes.

The device is not intended to provide direct diagnosis.

The device, including its labeling, includes complete cybersecurity controls developed in compliance with FDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023.

Indications for Use:

The AGADA SPINE Auto-Seg device is image processing software intended to provide qualitative information from analysis of previously acquired Computed Tomography (CT) DICOM images. The outputs of the software analysis are to be used to support spine surgeons in assessment of musculoskeletal diseases and surgical planning for adults 18 years of age and older. Product functions include; segmentation of thoracic and lumbar vertebrae and pelvis, and labelling of vertebra and pelvis objects.

The Auto-Seg device does not provide diagnosis nor recommend treatment and is to be used only as supporting information in clinical decision making.

The device is not intended for use with patients with spinal or pelvic implants.

Technological Characteristics Comparison:

Substantial Equivalence: The Auto-Seg is substantially equivalent to the Aprevo Digital Segmentation device cleared in K231955.

The 510(k) Substantial Equivalence Decision-making Process (detailed) from FDA Guidance - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] was followed as described below:

- The Auto-Seg device has the same intended use and similar indications for use as the Predicate device.
- The Auto-Seg device uses the same fundamental technology as the Predicate device and very similar detailed technological solutions as follows. Note, the Auto-Seg performs only a subset of functions of the predicate (e.g. segmentation).
 - Uses DICOM images of the target anatomy as system input
 - Performs segmentation of the input image using non-adaptive, machine learning algorithms.
 - Outputs of the segmentation algorithms are confirmed by the user prior to final device output.
 - The device output is used as an input to further surgical planning and clinical processes and is not a diagnostic device.
- The differences in scope of anatomy (spine + pelvis vs. spine only) are addressed by the selected reference device which also performs segmentation based radiological images including hip/pelvis.
- The differences in technological characteristics do not raise new types of questions of safety or effectiveness and were evaluated through comprehensive bench and usability verification and validation testing as discussed below.
- The results of testing provide assurance that the device is as safe and effective as the predicate.

For a more detailed comparison of characteristics, refer to the Substantial Equivalence comparison table included below.

Substantial Equivalence Comparison:

Device	Auto-Seg	Aprevo Digital Segmentation	Formus Hip	Conclusion
Characteristic	(Subject Device)	(Predicate Device, K231955)	(Reference Device, K213272)	
Intended Use	Intended as an image processing tool to support subsequent clinical workflows and surgical planning activities.	Intended as an image processing tool to support subsequent clinical workflows and surgical planning activities.	Intended to assist qualified medical professionals in the preoperative planning of orthopedic surgical procedures.	Identical to Predicate
Indications for Use	The AGADA SPINE Auto-Seg device is image processing software intended to provide qualitative information from analysis of previously acquired Computed Tomography (CT) DICOM images. The outputs of the software analysis are to be used to support spine surgeons in assessment of musculoskeletal diseases and surgical planning for adults 18 years of age and older. Product functions include; segmentation of thoracic and lumbar vertebrae and pelvis, and labelling of vertebra and pelvis objects. The Auto-Seg device does not provide diagnosis nor recommend treatment and is to be used only as supporting information in clinical decision making. The device is not intended for use with patients with spinal or pelvic implants.	Aprevo® Digital Segmentation software is intended to be used by trained, medically knowledgeable design personnel to perform digital image segmentation of the spine, primarily lumbar anatomy. The device inputs DICOM images and outputs a 3-D model of the spine.	Formus Hip is a pre-operative planning software for orthopedic surgery. The standalone software application imports patient diagnostic imaging studies (e.g. pre-dimensioned CT scans) from PACS-systems or other conventional medias. The Formus Hip system contains an integrated database of orthopedic hip implant geometries that can be overlayed to assist surgeons in their planning of orthopedic hip surgeries. The software application further enables the healthcare professional to customize their preoperative planning by means of an interactive graphical user interface. Finalized plans can be printed to a PDF report. The qualified healthcare professional can digitally perform the surgical planning and also make it available as a printable report. Clinical judgment and experience with the software are required for its successful use.	Substantially Equivalent
Device Class	II	II	II	Identical to Predicate and Reference Device

Device	Auto-Seg	Aprevo Digital Segmentation	Formus Hip	Conclusion
Characteristic	(Subject Device)	(Predicate Device, K231955)	(Reference Device, K213272)	
Procodes	QIH	QIH	QIH	Identical to Predicate and Reference Device
Anatomy	Thoracic and Lumbar Spine and Pelvis	Spine	Hip (Pelvis)	Substantially Equivalent to Predicate and Reference Device
Patient Population	Adults, 18 years of age and older	Not Specified	Adults, 21 years of age and older	Substantially Equivalent
Target User	Spine Surgeon	Medically trained designers	Qualified Medical Professionals	Substantially Equivalent
Environment	Office	Not Specified	Office	Identical to Predicate
Procedure Hardware Platform	Personal Computer w/ GPU	Personal Computer w/ GPU	Personal Computer	Identical to Predicate
Key Functions	Segmentation and Labelling	Segmentation and Labelling	Segmentation, quantitative measurements, display of implant overlays	Identical to Predicate
3D Image Data Source	CT – DICOM	DICOM	DICOM	Subset of Predicate

Device	Auto-Seg	Aprevo Digital Segmentation	Formus Hip	Conclusion
Characteristic	(Subject Device)	(Predicate Device, K231955)	(Reference Device, K213272)	
SaMD	Yes	Yes	Yes	Identical to Predicate and Reference Device
Algorithm Type	AI/ML Model	AI/ML Model	AI/ML Model	Identical to Both
Support for Editing Segmentation	No	No	Yes	Identical to Predicate
Device Outputs	3D models + 2D coronal and sagittal segmentation views	3D models	3D Models + Report	Substantially Equivalent

Table 1: Substantial Equivalence Comparison

AI-Enabled Software Functions:

The Auto-Seg software has two main AI/ML-based algorithms that reside in the Segmentation Algorithm software component. The first algorithm is responsible for segmentation of the lumbar and thoracic spine and contains three convolutional neural network (CNN) ML models within the algorithm. The second algorithm is responsible for pelvis segmentation and contains a single CNN ML model.

The data used for both spine and pelvis AI/ML models was comprised of 6 complete publicly available datasets with very broad demographic, CT scanner and institutional representation making them highly representative of the US intended use population. These databases were:

- a. CTSpine1K -COLONOG
- b. CTPelvic1K-COLONOG
- c. VerSe2019
- d. VerSe2020
- e. CTSpine1K - HNSCC-3DCT-RT
- d. Kits19

From the complete aggregate dataset, the cases were randomly split 60/20/20 into development, test, and validation datasets. No data was shared across these sets.

Spine Segmentation Algorithm:

The algorithm segments and localizes vertebrae with an iterative instance segmentation approach that detects, segments, and localizes vertebrae in a sequential, bottom-up approach.

The spine segmentation algorithm consists of three ML model elements that are combined in an iterative strategy. The central algorithm element is an individual vertebra segmentation neural network that segments voxels of vertebrae from a 3D image patch.

The training dataset for all models in this algorithm was 576 images

- a. CTSpine1K -COLONOG – 403 cases
- b. VerSe2019 / 2020 – 154 cases
- c. CTSpine1K - HNSCC-3DCT-RT – 19 cases

Pelvis Segmentation Algorithm:

The Pelvis Segmentation algorithm segments the entire CT image into different parts of the pelvis: right and left iliac, sacrum and the entire spine as a single unit. The central component is a deep learning model that segments voxels of the pelvis from a 3D image patch.

The training dataset for the pelvis segmentation model was 592 images:

- a. CTPelvic1K-COLONOG – 393 cases
- b. VerSe2019 / 2020 - 154 cases
- c. CTSpine1K - HNSCC-3DCT-RT – 26 cases

d. Kits19 – 19 cases

The combined algorithms return binary masks of the input images that identify which voxels in the image correspond to vertebra and pelvis objects. This information is then used to output individual object segmentation files in STL and NIfTI format to the USB drive.

Non-Clinical Performance Data:

There are no identified special controls or performance standards for this device.

The device has been designed and tested in conformance to the following voluntary recognized consensus standards.

- ISO 14971:2019 Medical Devices: Application of Risk Management to Medical Devices (FDA Recognition #5-125)
- ISO 15223:2021 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements (FDA Recognition #5-134)
- NEMA PS 3.1 - 3.20 (2023) Digital Imaging and Communications in Medicine (DICOM) Set (FDA Recognition #13-352)

The Auto-Seg software was verified and validated in accordance with 21 CFR 820.30 and subjected to both Safety and Cybersecurity Risk Management processes in accordance with ISO 14971 and FDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023.

The following tests were completed to demonstrate substantial equivalence and that any technological differences do not raise new or different questions of safety and effectiveness. The device successfully completed all of the evaluations and testing shown below. The standards shown above were used, where applicable, to design and conduct testing and evaluate results.

- Software Verification / Validation at the unit, integration and system levels
- Labeling Verification
- Risk Control Measure (safety and cybersecurity) verification of implementation and effectiveness
- Application Useability / Human Factors engineering principles and usability testing
- Cybersecurity Testing
- Stand-Alone Performance Assessment / Performance Validation
- Confirmatory Non-Inferiority Performance Validation

Stand-Alone Performance Assessment (SAPA)

As a part of the overall verification and validation for the Auto-Seg software, a Standalone Performance Assessment (SAPA) was developed in accordance with Performance Validation requirements from FDA draft guidance for Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations and SAPA requirements from FDA

guidance for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions as additional reference.

The databases of images used for the SAPA were randomly selected from the 6 publicly available databases listed above. To avoid bias, complete databases were downloaded. Once downloaded, images were screened to meet minimum system and study input requirements for:

- Containing patient age, sex, and disease state
- Meet CT images specifications
- Ground truth segmentation per an established, acceptable method was available with the dataset
- No implants are present in the images
- Patients were between the ages of 17 and 100 (18-99 inclusive)

The characteristics of the resulting validation datasets for the spine and pelvis images are shown in the two tables immediately below:

Characteristic	Subjects in Validation Dataset	Percent of Total
Total Quantity of Subjects	181	
Spine Dataset Subjects*	181	
Pelvis Dataset Subjects*	120	
Gender: Male	82	45%
Female	99	55%
Age 18-64	137	80%
Age 65>	44	20%
Disease State:		
Normal	102	56%
Degenerative Spondylolisthesis	19	11%
Degenerative Scoliosis	58	32%
Both Scoliosis and Spondylolisthesis	2	1%

Table 2: Validation Dataset Composition

* All members of the Pelvis Dataset were also present in the Spine Dataset

The data used in the SAPA had not been used for any other purpose. It was sequestered in an isolated location within the AGADA case data management system and no modifications to the images were made.

The study was split into two separate sets of evaluations (arms), one for spine objects and one for pelvis objects. The two study arms included some images that were

shared. However, no anatomical object was analyzed by both arms resulting in no duplicate results.

Segmentation accuracy performance, labeling accuracy, and timing performance of the Auto-Seg software were evaluated in the SAPA against established performance specifications and found to meet all specifications. The following tables present the results of the SAPA.

For the purposes of evaluating segmentation performance, the DICE coefficient was used to compare ground truth and segmentation masks provided by AutoSeg. The DICE coefficient is the most commonly used performance metric when evaluating segmentation performance. The mean of DICE coefficients (MDC) for each grouping along with the lower 95% confidence interval associated with the calculated mean was determined and is presented below for overall Auto-Seg performance and for individual subgroups.

Characteristic / Study Endpoint	Test / Evaluation	Sample Size	Acceptance Criteria	Result
Aggregate Labeling Accuracy	Comparison of model results to ground truth	1898	$\geq 99\%$ accuracy with 95% confidence	99.6%
Pelvis Labeling Accuracy	Comparison of model results to ground truth	357	$\geq 99\%$ accuracy with 95% confidence	100%
Spine Labeling Accuracy	Comparison of model results to ground truth	1541	$\geq 99\%$ accuracy with 95% confidence	99.6%
Thoracic and Lumbar Spine Object Segmentation Accuracy	Comparison of model segmentation output to ground truth using DICE coefficient for volumes	22	95% LCI of mean DICE coefficient for each spine object across entire population ≥ 0.80	Min 95%LCI from L5-T1 was @ T1 = 0.93323
		1898	95% LCI of mean DICE coefficient for all spine objects in aggregate for each subgroup ≥ 0.80	0.96025
Pelvis Object Segmentation Accuracy	Comparison of model segmentation output to ground truth using DICE coefficient for volumes	119	95% LCI of mean DICE coefficient for each pelvis object across entire population ≥ 0.80	Min 95%LCI from Pelvis was @ Sacrum = 0.96888
		357	95% LCI of mean DICE coefficient for all pelvis objects in aggregate for each subgroup ≥ 0.80	0.97312
Segmentation Duration	Comparison of time to segment an image to established performance specification	30	Segmentation time for an image shall be less than 40 seconds per vertebra and 100 seconds for the entire pelvis. 90%C / 90%R	UTL _s = 15.7s UTL _p = 24.6s
			Total Segmentation Time <10 min (90%C/90%R) <13 min (90%C/99%R)	Spine Dataset UTL _{s90/90} = 3.9m UTL _{s90/99} = 6.1m Pelvis Dataset UTL _{p90/90} = 3.7m UTL _{p90/99} = 5.2m

Table 3: SAPA Device Performance Data

As a part of the performance validation, subgroup MDC analysis using Age, Sex, CT scanner manufacturer, individual segmentation objects, disease state, estimated bone mineral density (BMD), and object size was performed. Each subgroup performed similar to overall aggregate populations, and no subgroup showed a clinically significant degradation of performance.

No animal or prospectively gathered human clinical data were needed to demonstrate substantial equivalency

Confirmatory Non-Inferiority Performance Validation

To supplement the original SAPA, an additional performance validation study was completed using 54 subjects from four additional clinical sites that were not a part of the original training, testing or validation datasets. The purpose of this study was to show the original performance validation results were extensible to sites independent of the original training / tuning / validation dataset.

Characteristic	Subjects in Validation Dataset	Percent of Total
Total Quantity of Subjects	54	
Spine Dataset Subjects*	54	
Pelvis Dataset Subjects*	53	
Sex: Male	30	56%
Sex: Female	24	44%
Age: >18 and <=64	42	78%
Age: >=64	12	22%
Degenerative Scoliosis	14	26%
Degenerative Spondylolisthesis	11	20%
None	29	54%

Table 4: Validation Dataset Composition

* All members of the Pelvis Dataset were also present in the Spine Dataset

The primary endpoint of the study was non-inferiority of Auto-Seg DICE score performance based on newly gathered data when compared to the original SAPA data (10% NI margin, 80% power, $\alpha=0.025$). Secondary endpoints of the study included segmentation accuracy performance and timing performance of the Auto-Seg software against established performance specifications. Thirteen individual subjects / cases were determined as statistical outliers for various groups. As a result, Primary (inclusive of outliers) and Sensitivity Analysis (outliers removed) were performed.

Primary and secondary endpoints for the study were all met for Primary and Sensitivity Analyses. Results of the study showed non-inferior results for all aggregate and individual object performance. Further, secondary endpoints all showed compliance with established performance specifications. The following table summarizes the Primary Analysis results:

Characteristic / Study Endpoint	Test / Evaluation	Sample Size	Acceptance Criteria	Result
Thoracic and Lumbar Spine Object Segmentation Accuracy	Non-Inferiority Hypothesis Testing	11 to 54 / 4 to 41 depending on object	Non-inferiority for each spine object (T1–T12 and L1–L5), met if the two-sided 95% UCI for the difference	All individual objects found non-inferior

Characteristic / Study Endpoint	Test / Evaluation	Sample Size	Acceptance Criteria	Result
	(Primary / Sensitivity Analysis)		is less than 0.10 (10%) per object.	
		582 / 389	Non-inferiority for the aggregate MDC across all aggregate vertebrae, met if the 95% UCI for the difference is less than 0.10 (10%).	Aggregate spine found non-inferior
Pelvis Object Segmentation Accuracy	Non-Inferiority Hypothesis Testing (Primary / Sensitivity Analysis)	53 / 40	Non-inferiority for each pelvis object (sacrum, Pelvis-L, Pelvis-R), met if the two-sided 95% UCI for the difference is less than 0.10 (10%) per object.	All individual objects found non-inferior
		158 / 120	Non-inferiority for the aggregate MDC across all aggregate pelvis objects, met if the 95% UCI for the difference is less than 0.10 (10%).	Aggregate pelvis found non-inferior
Thoracic and Lumbar Spine Object Segmentation Accuracy	Comparison of model segmentation output to ground truth using DICE coefficient for volumes. (Primary / Sensitivity Analysis)	11 to 54 / 4 to 41 depending on object	95% LCI of mean DICE coefficient for each spine object across entire population ≥ 0.80	Primary: Min 95%LCI from L5-T1 was @ T3 = 0.9021
				Sensitivity: Min 95%LCI from L5-T1 was @ T1 = 0.9217
		582 / 389	95% LCI of mean DICE coefficient for all spine objects in aggregate for each subgroup ≥ 0.80	Primary: 0.9399
				Sensitivity: 0.95012
Pelvis Object Segmentation Accuracy	Comparison of model segmentation output to ground truth using DICE coefficient for volumes. (Primary / Sensitivity Analysis)	53 / 40	95% LCI of mean DICE coefficient for each pelvis object across entire population ≥ 0.80	Primary: Min 95%LCI for Pelvis was @ Sacrum = 0.9517
				Sensitivity: Min 95%LCI for Pelvis was @ Sacrum = 0.9579
		158 / 120	95% LCI of mean DICE coefficient for all pelvis objects in aggregate for each subgroup ≥ 0.80	Primary: 0.9575
				Sensitivity: 0.9614
Segmentation Duration	Comparison of time to segment an image to established performance specification	30	Segmentation time for an image shall be less than 40 seconds per vertebra and 100 seconds for the entire pelvis. 90%C / 90%R	UTL _s = 9.70s UTL _p = 6.64s
			Total Segmentation Time <10 min (90%C/90%R) <13 min (90%C/99%R)	Spine Dataset UTL _{s90/90} = 2.6m UTL _{s90/99} = 4.3m Pelvis Dataset UTL _{p90/90} = 3.0m UTL _{p90/99} = 5.2m

Table 4: Confirmatory Performance Validation NI Study Results

Substantial Equivalence Conclusion:

The results of the comparison of the Auto-Seg to the predicate device, in conjunction with the successful performance validation data gathered and described above, show the Auto-Seg has the same intended use, similar technological characteristics, and that the differences in technological characteristics do not raise different questions of safety and effectiveness. Therefore, it is concluded that the Auto-Seg is substantially equivalent to the Aprevo Digital Segmentation (K231955).