



September 9, 2025

Springbok, Inc. (dba Springbok Analytics)
Scott Magargee
Chief Executive Officer
110 Old Preston Avenue
Charlottesville, Virginia 22902

Re: K251682
Trade/Device Name: MuscleView 2.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: August 1, 2025
Received: August 1, 2025

Dear Scott Magargee:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue 'FDA' watermark.

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.

K251682

?

Please provide the device trade name(s).

?

MuscleView 2.0

Please provide your Indications for Use below.

?

MuscleView 2.0 is a magnetic resonance diagnostic software device used in adults and pediatrics aged 18 and older which automatically segments muscle, bone, fat and other anatomical structures from magnetic resonance imaging. After segmentation, it enables the generation, display and review of magnetic resonance imaging data. The segmentation results need to be reviewed and edited using appropriate software. Other physical parameters derived from the images may also be produced. This device is not intended for use with patients who have tumors in the trunk, arms and/or lower limb(s).

When interpreted by a trained clinician, these images and physical parameters may yield information that may assist in diagnosis.

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)

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18.1 – 510(k) Summary

09/02/2025

Applicant

K251682

Scott Magargee
Chief Executive Officer
Springbok, Inc.
110 Old Preston Ave
Charlottesville, VA 22902 USA
Phone: 1-215-680-9078
Email: scott.magargee@springbokanalytics.com

Device Information

Trade Name: MuscleView 2.0
Regulation: 892.1000 – Magnetic Resonance Diagnostic Device
Product Code: LNH (Class 2) – System, Nuclear Magnetic Resonance Imaging

Intended Use

MuscleView uses Artificial Intelligence/Machine Learning (AI/ML) algorithms to automatically segment anatomical structures in magnetic resonance imaging data. This segmentation and the associated metrics are intended to assist healthcare professionals in the visualization and quantification of anatomical structures.

Indications for Use

MuscleView 2.0 is a magnetic resonance diagnostic software device used in adults and pediatrics aged 18 and older which automatically segments muscle, bone, fat and other anatomical structures from magnetic resonance imaging. After segmentation, it enables the generation, display and review of magnetic resonance imaging data. The segmentation results need to be reviewed and edited using appropriate software. Other physical parameters derived from the images may also be produced. This device is not intended for use with patients who have tumors in the trunk, arms and/or lower limb(s).

When interpreted by a trained clinician, these images and physical parameters may yield information that may assist in diagnosis.

Device Description

MuscleView 2.0 is a software-only medical device which performs automatic segmentation of musculoskeletal structures. The software utilizes a locked artificial intelligence/machine learning (AI/ML) algorithm to identify and segment anatomical structures for quantitative analysis. The input to the software is DICOM data from magnetic resonance imaging (MRI), but the subject device does not directly interface with any devices. The output includes volumetric and dimensional metrics of individual and grouped regions of interest (ROIs) (such as muscles, bones and adipose tissue) and comparative analysis against a Virtual Control Group (VCG) derived from reference population data.

MuscleView 2.0 builds upon the predicate device, MuscleView 1.0 (K241331, cleared 10/01/2024), which was cleared for the segmentation and analysis of lower extremity structures (hips to ankles). The subject device extends functionality to include:

- Upper body regions (neck to hips)
- Adipose tissue segmentation (subcutaneous, visceral, intramuscular, and hepatic fat)
- Quantitative comparison with a Virtual Control Group
- Additional derived metrics including Z-scores and composite scores (e.g., muscle-bone score)

The submission includes a Predetermined Change Control Plan which details the procedure for retraining AI/ML algorithms or adding data to the Virtual Control Groups in order to improve performance without negatively impacting the safety or efficacy of the device.

Predicate Device Information

Trade Name: MuscleView 1.0

510K Number: K241331

Regulation: 892.1000 – Magnetic Resonance Diagnostic Device

Product Code: LNH (Class 2) – System, Nuclear Magnetic Resonance Imaging

Reference Device Information

Trade Name: AMRA Profiler

510K Number: K211983

Regulation: 892.1000 – Magnetic Resonance Diagnostic Device

Product Code: LNH (Class 2) – System, Nuclear Magnetic Resonance Imaging

AI/ML Model Cards

Model	Release Date	Anatomical Region	Model Function
MuscleView 2.0	05/30/2025	Full Body	Assistive AI
Model Training and Testing The MuscleView 2.0 – Setting 1 model underwent supervised machine learning using a curated collection of retrospective MRI datasets from a diverse population (n = 1294 unique subjects). Each dataset was labeled through a consensus process by expert segmentation analysts to establish ground truth. The model was tested on diverse datasets (n = 148 unique subjects) independent from the training datasets and blinded to ground truth segmentations. Performance results demonstrated segmentation accuracy within the interobserver variability range observed among experts. Model Settings All AI/ML inferences are performed automatically, with no configuration, calibration or exposed modifiable parameters. The model behavior is locked and deterministic. Privacy Patient data is kept within the user’s network and is not used to train or test future models.			

Predicate Device Comparison

Attribute	Subject Device	Predicate Device	Reference Device	Comment
Device Name	MuscleView 2.0	MuscleView 1.0	AMRA Profiler	n/a
Manufacturer	Springbok, Inc.	Springbok, Inc.	AMRA	n/a
510(k) Number	TBD	K241331	K211983	n/a
Regulation	892.1000	892.1000	892.1000	No difference
Product Code	LNH	LNH	LNH	No difference

Attribute	Subject Device	Predicate Device	Reference Device	Comment
Indications for Use	MuscleView is a magnetic resonance diagnostic software device which automatically segments muscle, bone, fat and other anatomical structures from magnetic resonance imaging. After segmentation, it enables the generation, display and review of magnetic resonance imaging data. Other physical parameters derived from the images may also be produced. When interpreted by a trained clinician, these images and physical parameters may yield information that may assist in diagnosis.	MuscleView is intended for use in adults and pediatric patients aged 18 years and older to automatically segment muscle and bone structures of the lower extremities from magnetic resonance imaging using a machine learning-based approach. Following segmentation, it provides derived metrics including muscle volume, bone volume, intramuscular fat percentage, and left/right asymmetry. The software is intended to be used by physicians trained in the interpretation of MRI images and serves as an initial method for segmenting muscle and bone structures from one or more study series. Segmentation results must be reviewed and, if necessary, edited using appropriate software. MuscleView is intended solely to provide segmentation and derived metrics for muscle and bone structures and is not intended to directly support the diagnosis of any disease. This device is not intended for use in patients with tumors in the lower limbs.	Indicated for use as a magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation, this device enables the generation, display, and review of 2D magnetic resonance medical image data. It is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets acquired from compatible MR systems to display the internal structure of the body, including the liver. Other physical parameters derived from the images may also be produced. The software provides a number of quantification tools, such as Region of Interest (ROI) placements, to be used for the assessment of regions within an image to quantify liver tissue characteristics, including the determination of fat fraction in the liver, T2*, and muscle volume. These images and the physical parameters derived from them, when interpreted by a trained clinician, yield information that may assist in diagnosis.	The subject device expands upon the capabilities of the predicate device by supporting segmentation and analysis of a broader range of anatomical regions of interest (ROIs), including ROIs in the upper body and different types of adipose tissue. Furthermore, the subject device includes a comparative function similar to that of the reference device, enabling comparison of patient-specific metrics to a virtual control group.
Anatomy	Muscles, bones and fat structures in the legs, trunk and arms.	Muscles, bones and fat structures in the legs.	Muscles, bones and fat structures in the legs	
Intended Users	Trained clinicians	Trained clinicians	Trained clinicians	No difference
Target Population	Adults and pediatric patients aged 18 and older	Adults and pediatric patients aged 18 and older	Adults	No difference
Contra-indications	Tumors in the trunk, arms and/or lower limbs	Tumors in the lower extremities	None, software only	Subject device contraindications reflect the expanded indications for use from the predicate device.
Imaging modality	Magnetic Resonance Imaging	Magnetic Resonance Imaging	Magnetic Resonance Imaging	No difference
MRI Scanners	GE, Siemens, Philips	GE, Siemens, Philips	GE, Siemens, Philips	No difference
MR Field Strength	1.5T, 3.0T	1.5T, 3.0T	1.5T, 3.0T	No difference

Software Testing

MuscleView 2.0 has been tested in alignment with the FDA's guidance on software functions ("Content of Premarket Submissions for Device Software Functions", June 14, 2023) and cybersecurity ("Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", September 27, 2023). It has successfully met the predetermined acceptance criteria for the following tests:

- Unit Testing
- Integration Testing
- Cybersecurity Testing
- Software Verification
- Software Validation

Performance Testing

To evaluate the performance of the MuscleView AI segmentation algorithm, a comprehensive test was conducted using a test set that was fully independent from the training set. The AI was blinded to the ground truth segmentation labels during inference, ensuring an unbiased comparison. De-identified subject scans were included in the test cohort. The cohort was demographically diverse, including both male and female participants across a range of age groups and body mass indices (BMI), and scans acquired from multiple imaging sites and MRI manufacturers (Siemens, GE, Philips) to ensure clinical applicability.

MRI Manufacturers
GE
Siemens
Philips
Cannon
Toshiba
(AI Model Setting 1 only)

Biological Sex & Age
Males 18-21
Males over 21
Females 18-21
Females over 21

Patient Population
Healthy Adult/Athlete
Patient

Performance testing of segmentation and associated metrics was performed by comparing the results obtained to a reference standard developed by manual segmentation performed by experts. Validation Tests met the acceptance criteria if the dice similarity coefficient (DSC) or volume difference (VDt) was below interobserver variability, establishing boundaries that reflect clinically acceptable variance among expert human reviewers. The AI model's performance was consistently within these predefined interobserver ranges for nearly all ROIs evaluated.

These results demonstrate that the AI segmentation system performs at a level equivalent to expert human annotation, with robustness confirmed across imaging vendors, patient populations, and anatomical diversity. This supports the generalizability of the model for clinical deployment in a wide variety of real-world imaging environments and patient demographics.

Summary of AI Training & Testing Dataset

The AI responsible for muscle segmentation within MuscleView was trained and tested on MRI scans generated across varying patients, demographics (including – but not limited to – gender, age and ethnicity), scan sites, and MRI parameters (including manufacturer, magnetic field strength, series settings/types, matrix size, field of view, and scan resolution). See the table below detailing variation in the data.

Factor	Groups	AI Setting 1 (Lower Extremity)		AI Setting 2 & 3 (Upper extremity and Adipose Tissue)	
		Training data	Validation data	Training data	Validation data
Number of unique scans	n/a	1658	148	392	171
Number of unique subjects	n/a	1294	148	209	171
Gender	Male	1192*	102	230*	96*
	Female	374*	46	156*	74*
Age*	Mean	29	31.7	41.8	39.3
	Standard Deviation	13.4	15.5	19.4	17.7
Ethnicity (based on regional demographics)	% Non-Hispanic White	52	52	50	50
	% Hispanic/Latino	18	18	17	15
	% Black/African American	14	14	11	14
	% Asian	10	10	13	7
	% Australian	2	2	3	6
	% American Indian / Alaska Native	<1	<1	<1	<1
	% Native Hawaiian / Pacific Islander	<1	<1	<1	<1
	% Australian Aboriginal	<1	<1	<1	1
	% Other	2	2	2	3
MRI Manufacturer	Siemens	680	74	293	116
	GE Medical Systems	435	28	54	26
	Philips Medical Systems	82	29	41	25
	Canon	1	4	0	3
	Other (Toshiba) or Unknown	460	13	4	1

* Demographic data were not available for some scans.

Independence of test data from training data was ensured in several ways. (1) MRI Data used to train the AI was explicitly separate from validation data (both as MRI scans and as subjects), (2) the majority (70% - 84%) of datasets in the validation set came from imaging centers and organizations not used in the train datasets (19 – 22 new sites), and (3) the personnel involved in establishing the reference standard for the AI were not involved in the algorithm's development to ensure the independence of training and testing.

The three AI settings responsible for the segmentation of 172 ROIs - setting 1 (lower extremity), setting 2 (upper extremity), and setting 3 (adipose tissue) - were validated, demonstrating their accuracy across many varying scan and patient cases as related to the gold-standard of label generation – interobserver

repeatability of manually vetted labels. AI setting 1 consisted of a separate training and testing set than settings 2 & 3. The segmentation performance and derived metrics of all ROIs passed the predetermined acceptance criteria in both healthy and patient population subgroups, i.e. a one-sample T-test between the results of the validation set and the acceptance criteria threshold (the 95% confidence interval from the interobserver repeatability of manually vetted labels with a buffer if applicable). A desired outcome to “approve” a ROI passed validation was a mean better than or equal to the acceptance criteria (a significant T-test showing the sample differed significantly better than the acceptance criteria threshold). Each musculoskeletal structure either used dice similarity coefficient (DSC) or volume difference (VDt) as its comparison metric, dependent on what best captured the structure’s segmentation accuracy. A healthy and patient subgroup analysis split the validation dataset into two groups, healthy (athlete and healthy control) and patients (amputees, muscular dystrophy patients, and patient post-surgery). The subgroup analysis across different manufacturers; GE, Siemens, Phillips, Toshiba (AI setting 1), Canon; also showed consistent performance, indicating high generalizability of our product. The age/biologic sex subgroup analysis (males 18 – 21 years old, females 18 – 21 years old, males >21 years old, and females >21 years old) also demonstrated that each subgroup passed the predetermined acceptance criteria. For the 95% confidence interval for all structures and subgroups, see **Table 1** (DSC) and **Table 2** (VDt).

Table 1: The 95% confidence interval for the ROIs in AI settings 1-3 for the DICE (DSC) metric.

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Canon	GE	Phillips	Siemens	Toshiba	Male 18-21 Years	Male Over 21 Years	Female 18-21 years	Female Over 21 years
adductor brevis	0.962 -0.965	0.909 -0.932	0.978 -0.984	0.947 -0.967	0.937 -0.954	0.941 -0.954	0.956 -0.96	0.956 -0.969	0.95 -0.959	0.958 -0.963	0.911 -0.941
adductor longus	0.978 -0.979	0.934 -0.952	0.982 -0.989	0.965 -0.98	0.954 -0.972	0.962 -0.971	0.971 -0.975	0.97 -0.982	0.968 -0.975	0.974 -0.978	0.936 -0.96
adductor magnus	0.988 -0.989	0.963 -0.974	0.994 -0.997	0.981 -0.992	0.976 -0.986	0.979 -0.984	0.981 -0.985	0.984 -0.991	0.982 -0.987	0.987 -0.99	0.968 -0.978
biceps femoris: long head	0.981 -0.982	0.946 -0.964	0.976 -0.995	0.975 -0.985	0.964 -0.977	0.967 -0.976	0.975 -0.98	0.972 -0.983	0.97 -0.978	0.979 -0.982	0.956 -0.974
biceps femoris: short head	0.96 -0.969	0.88 -0.931	0.827 -1.025	0.919 -0.979	0.93 -0.967	0.936 -0.955	0.951 -0.957	0.967 -0.972	0.943 -0.961	0.953 -0.96	0.887 -0.94
external rotators	0.867 -0.876	0.809 -0.834	0.884 -0.909	0.821 -0.851	0.846 -0.867	0.852 -0.867	0.869 -0.883	0.868 -0.881	0.861 -0.874	0.843 -0.861	0.809 -0.837
femur	0.987 -0.99	0.979 -0.984	0.921 -0.985	0.983 -0.991	0.986 -0.989	0.986 -0.988	0.988 -0.989	0.99 -0.992	0.984 -0.988	0.989 -0.991	0.981 -0.985
fibula	0.914 -0.927	0.797 -0.852	0.941 -0.958	0.904 -0.919	0.909 -0.924	0.858 -0.895	0.856 -0.94	0.918 -0.931	0.902 -0.92	0.867 -0.919	0.773 -0.86
fibulari	0.961 -0.969	0.918 -0.946	0.978 -0.983	0.962 -0.97	0.956 -0.968	0.942 -0.96	0.922 -0.972	0.963 -0.972	0.957 -0.966	0.939 -0.97	0.91 -0.954
flexor digitorum longus	0.863 -0.882	0.827 -0.851	0.905 -0.935	0.855 -0.874	0.853 -0.875	0.863 -0.88	0.76 -0.875	0.875 -0.898	0.869 -0.882	0.793 -0.864	0.822 -0.857
flexor hallucis longus	0.94 -0.952	0.869 -0.909	0.963 -0.976	0.94 -0.953	0.932 -0.942	0.91 -0.936	0.879 -0.956	0.949 -0.956	0.926 -0.942	0.907 -0.956	0.871 -0.927
Gastrocnemius: lateral head	0.972 -0.974	0.922 -0.949	0.982 -0.986	0.969 -0.976	0.955 -0.973	0.947 -0.964	0.966 -0.97	0.97 -0.976	0.953 -0.969	0.97 -0.974	0.938 -0.962
Gastrocnemius: medial head	0.979 -0.983	0.928 -0.955	0.991 -0.993	0.979 -0.985	0.969 -0.98	0.951 -0.969	0.971 -0.981	0.972 -0.985	0.96 -0.976	0.977 -0.984	0.949 -0.969
gluteus maximus	0.993 -0.994	0.977 -0.985	0.998 -0.998	0.99 -0.995	0.99 -0.993	0.985 -0.99	0.993 -0.994	0.991 -0.995	0.988 -0.993	0.994 -0.995	0.983 -0.988
gluteus medius	0.985 -0.987	0.966 -0.975	0.993 -0.995	0.981 -0.989	0.977 -0.983	0.977 -0.982	0.983 -0.985	0.983 -0.988	0.98 -0.984	0.985 -0.988	0.97 -0.979
gluteus minimus	0.964 -0.966	0.929 -0.946	0.974 -0.982	0.949 -0.966	0.951 -0.959	0.951 -0.96	0.957 -0.963	0.965 -0.969	0.954 -0.963	0.959 -0.965	0.937 -0.95
gracilis	0.969 -0.971	0.907 -0.939	0.964 -0.986	0.94 -0.972	0.956 -0.97	0.943 -0.961	0.955 -0.962	0.97 -0.976	0.95 -0.967	0.959 -0.965	0.927 -0.949
iliacus	0.974 -0.976	0.94 -0.96	0.986 -0.989	0.967 -0.979	0.965 -0.971	0.958 -0.97	0.967 -0.971	0.976 -0.98	0.964 -0.974	0.971 -0.975	0.94 -0.964
obturator externus	0.927 -0.934	0.881 -0.904	0.945 -0.96	0.893 -0.921	0.901 -0.924	0.918 -0.929	0.924 -0.939	0.916 -0.938	0.92 -0.931	0.919 -0.931	0.893 -0.913
obturator internus	0.881 -0.889	0.815 -0.855	0.895 -0.919	0.836 -0.865	0.856 -0.885	0.863 -0.885	0.869 -0.889	0.889 -0.902	0.875 -0.891	0.85 -0.865	0.803 -0.855
pectineus	0.946 -0.952	0.894 -0.923	0.965 -0.974	0.927 -0.952	0.908 -0.933	0.932 -0.947	0.943 -0.95	0.952 -0.963	0.938 -0.948	0.943 -0.947	0.883 -0.924
pelvis	0.978 -0.981	0.952 -0.964	0.989 -0.992	0.968 -0.982	0.969 -0.977	0.968 -0.974	0.979 -0.981	0.98 -0.984	0.971 -0.977	0.978 -0.983	0.956 -0.967
phalangeal extensors	0.948 -0.958	0.879 -0.912	0.967 -0.977	0.946 -0.957	0.942 -0.954	0.917 -0.939	0.896 -0.963	0.953 -0.959	0.932 -0.947	0.918 -0.96	0.892 -0.938

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Canon	GE	Philips	Siemens	Toshiba	Male 18-21 Years	Male Over 21 Years	Female 18-21 years	Female Over 21 years
piriformis	0.917 -0.936	0.88 -0.908	0.938 -0.959	0.865 -0.932	0.894 -0.924	0.917 -0.929	0.919 -0.935	0.883 -0.949	0.923 -0.932	0.914 -0.927	0.873 -0.912
popliteus	0.863 -0.889	0.846 -0.865	0.889 -0.911	0.852 -0.868	0.873 -0.887	0.849 -0.89	0.857 -0.876	0.895 -0.906	0.854 -0.895	0.84 -0.852	0.837 -0.854
psoas major	0.98 -0.982	0.943 -0.965	0.989 -0.993	0.974 -0.984	0.976 -0.98	0.961 -0.974	0.975 -0.979	0.979 -0.984	0.969 -0.98	0.978 -0.982	0.944 -0.97
quadratus femoris	0.905 -0.915	0.774 -0.833	0.859 -0.962	0.871 -0.903	0.876 -0.908	0.848 -0.887	0.867 -0.907	0.914 -0.925	0.878 -0.907	0.884 -0.9	0.759 -0.833
quadratus lumborum	0.926 -0.933	0.865 -0.896	0.93 -0.951	0.903 -0.924	0.914 -0.932	0.895 -0.917	0.922 -0.931	0.922 -0.944	0.911 -0.93	0.902 -0.919	0.87 -0.898
rectus femoris	0.982 -0.985	0.915 -0.946	0.947 -0.992	0.972 -0.988	0.949 -0.976	0.955 -0.972	0.98 -0.983	0.97 -0.988	0.962 -0.976	0.983 -0.986	0.923 -0.965
sartorius	0.974 -0.976	0.928 -0.952	0.984 -0.987	0.958 -0.978	0.956 -0.974	0.955 -0.967	0.968 -0.971	0.976 -0.98	0.963 -0.972	0.97 -0.974	0.927 -0.958
semimembranosus	0.983 -0.985	0.912 -0.959	0.991 -0.993	0.934 -0.994	0.955 -0.976	0.969 -0.979	0.975 -0.98	0.98 -0.986	0.971 -0.981	0.981 -0.984	0.943 -0.967
semitendinosus	0.982 -0.984	0.939 -0.964	0.988 -0.992	0.962 -0.987	0.969 -0.981	0.968 -0.978	0.973 -0.978	0.979 -0.987	0.975 -0.982	0.977 -0.981	0.946 -0.971
soleus	0.982 -0.986	0.937 -0.958	0.993 -0.995	0.983 -0.99	0.968 -0.981	0.962 -0.975	0.964 -0.984	0.98 -0.985	0.97 -0.98	0.975 -0.989	0.943 -0.968
tensor fasciae latae	0.955 -0.959	0.907 -0.937	0.943 -0.974	0.948 -0.956	0.939 -0.958	0.934 -0.953	0.943 -0.956	0.958 -0.965	0.939 -0.957	0.94 -0.95	0.919 -0.942
tibia	0.98 -0.984	0.966 -0.974	0.993 -0.994	0.976 -0.983	0.979 -0.984	0.975 -0.98	0.958 -0.986	0.982 -0.986	0.98 -0.983	0.966 -0.983	0.966 -0.976
tibialis anterior	0.965 -0.972	0.914 -0.94	0.979 -0.985	0.964 -0.971	0.959 -0.969	0.941 -0.96	0.931 -0.972	0.96 -0.977	0.956 -0.967	0.944 -0.97	0.917 -0.955
tibialis posterior	0.957 -0.965	0.938 -0.95	0.973 -0.98	0.953 -0.965	0.955 -0.96	0.954 -0.961	0.912 -0.968	0.962 -0.968	0.957 -0.962	0.932 -0.968	0.941 -0.954
vastus intermedius	0.98 -0.981	0.91 -0.955	0.99 -0.994	0.925 -0.992	0.958 -0.978	0.961 -0.971	0.971 -0.976	0.97 -0.985	0.967 -0.977	0.977 -0.982	0.942 -0.962
vastus lateralis	0.991 -0.992	0.96 -0.979	0.992 -0.998	0.97 -0.997	0.98 -0.99	0.982 -0.987	0.987 -0.99	0.985 -0.994	0.984 -0.989	0.991 -0.994	0.977 -0.984
vastus medialis	0.988 -0.99	0.947 -0.973	0.962 -0.995	0.968 -0.998	0.975 -0.986	0.977 -0.985	0.979 -0.987	0.984 -0.993	0.979 -0.987	0.988 -0.99	0.965 -0.978
patella	0.831 -0.850	0.809 -0.83	0.587 -0.899	0.808 -0.829	0.818 -0.838	0.845 -0.860	0.791 -0.836	0.860 -0.875	0.834 -0.858	0.804 -0.818	0.771 -0.802
sacrum	0.934 -0.964	0.863 -0.918	0.978 -0.987	0.951 -0.978	0.882 -0.949	0.901 -0.943	0.877 -0.994	0.938 -0.977	0.894 -0.939	0.971 -0.978	0.868 -0.951
rectus abdominis	0.878 -0.893	0.811 -0.852	0.879 -0.965	0.869 -0.899	0.827 -0.871	0.869 -0.887		0.859 -0.896	0.874 -0.898	0.875 -0.912	0.845 -0.870
external oblique	0.850 -0.866	0.753 -0.823	0.883 -0.908	0.819 -0.866	0.747 -0.827	0.848 -0.866		0.876 -0.903	0.858 -0.878	0.780 -0.859	0.786 -0.825
levator scapulae	0.863 -0.876	0.798 -0.852	0.800 -0.883	0.835 -0.870	0.811 -0.858	0.863 -0.878		0.878 -0.909	0.863 -0.881	0.819 -0.872	0.827 -0.854
supraspinatus	0.903 -0.915	0.862 -0.901	0.912 -0.929	0.896 -0.916	0.868 -0.911	0.899 -0.913		0.923 -0.942	0.907 -0.926	0.859 -0.895	0.872 -0.892
trapezius	0.912 -0.922	0.791 -0.852	0.899 -0.941	0.905 -0.924	0.773 -0.843	0.912 -0.922		0.915 -0.946	0.896 -0.918	0.877 -0.907	0.867 -0.896
rhomboid	0.889 -0.900	0.812 -0.865	0.886 -0.923	0.891 -0.911	0.811 -0.867	0.882 -0.897		0.893 -0.932	0.881 -0.903	0.859 -0.894	0.855 -0.877
erector spinae	0.951 -0.957	0.914 -0.939	0.947 -0.954	0.940 -0.952	0.909 -0.939	0.952 -0.958		0.958 -0.972	0.949 -0.957	0.937 -0.956	0.931 -0.945
multifidus	0.916 -0.935	0.846 -0.919	0.809 -0.946	0.883 -0.935	0.820 -0.911	0.922 -0.941		0.940 -0.959	0.892 -0.929	0.918 -0.953	0.893 -0.929
serratus anterior	0.893 -0.905	0.856 -0.893	0.911 -0.920	0.919 -0.937	0.858 -0.897	0.882 -0.897		0.935 -0.953	0.898 -0.914	0.860 -0.891	0.853 -0.874
latissimus dorsi	0.944 -0.951	0.883 -0.917	0.949 -0.961	0.941 -0.955	0.883 -0.923	0.940 -0.948		0.950 -0.974	0.939 -0.952	0.919 -0.937	0.916 -0.931
subscapularis	0.942 -0.949	0.938 -0.949	0.943 -0.955	0.938 -0.949	0.940 -0.953	0.941 -0.949		0.957 -0.967	0.947 -0.955	0.920 -0.937	0.929 -0.940
teres major	0.842 -0.864	0.806 -0.852	0.826 -0.899	0.843 -0.871	0.846 -0.880	0.829 -0.857		0.892 -0.919	0.854 -0.880	0.805 -0.843	0.789 -0.829
infraspinatus and teres minor	0.955 -0.961	0.942 -0.954	0.961 -0.968	0.948 -0.958	0.944 -0.958	0.954 -0.961		0.961 -0.971	0.956 -0.964	0.939 -0.954	0.945 -0.954
pectoralis minor	0.890 -0.901	0.836 -0.872	0.895 -0.908	0.877 -0.904	0.852 -0.891	0.883 -0.897		0.910 -0.938	0.888 -0.905	0.833 -0.874	0.861 -0.879
pectoralis major	0.935 -0.947	0.869 -0.910	0.807 -1.000	0.922 -0.948	0.864 -0.917	0.934 -0.946		0.950 -0.978	0.934 -0.953	0.897 -0.923	0.899 -0.922
deltoid	0.967 -0.972	0.946 -0.961	0.972 -0.973	0.965 -0.973	0.956 -0.971	0.962 -0.969		0.968 -0.982	0.963 -0.970	0.955 -0.969	0.957 -0.966
triceps brachii	0.975 -0.981	0.922 -0.967	0.979 -0.982	0.975 -0.982	0.968 -0.979	0.958 -0.976		0.978 -0.989	0.966 -0.979	0.966 -0.981	0.947 -0.975
coracobrachialis	0.880 -0.894	0.837 -0.877	0.880 -0.908	0.856 -0.881	0.850 -0.890	0.877 -0.895		0.883 -0.922	0.888 -0.905	0.852 -0.893	0.840 -0.865
biceps brachii	0.957 -0.963	0.931 -0.954	0.959 -0.964	0.950 -0.962	0.943 -0.961	0.953 -0.962		0.968 -0.979	0.956 -0.966	0.938 -0.958	0.938 -0.951
brachialis	0.939 -0.949	0.872 -0.935	0.931 -0.947	0.934 -0.951	0.926 -0.948	0.923 -0.945		0.956 -0.971	0.924 -0.952	0.911 -0.946	0.909 -0.932
brachioradialis	0.883 -0.899	0.778 -0.871	0.890 -0.931	0.878 -0.908	0.810 -0.888	0.874 -0.895		0.888 -0.946	0.884 -0.908	0.801 -0.864	0.829 -0.864
extensor carpi radialis	0.908 -0.920	0.814 -0.895	0.886 -0.911	0.890 -0.923	0.856 -0.913	0.904 -0.921		0.936 -0.951	0.908 -0.927	0.884 -0.908	0.852 -0.888
anconeus	0.755 -0.779	0.750 -0.813	0.824 -0.848	0.742 -0.780	0.742 -0.790	0.754 -0.785		0.807 -0.841	0.783 -0.811	0.680 -0.754	0.694 -0.733
digit extensors	0.881 -0.895	0.858 -0.900	0.866 -0.892	0.858 -0.900	0.873 -0.902	0.881 -0.897		0.916 -0.934	0.879 -0.901	0.862 -0.889	0.851 -0.872
extensor carpi ulnaris	0.818 -0.836	0.812 -0.861	0.816 -0.866	0.818 -0.850	0.833 -0.862	0.808 -0.832		0.867 -0.892	0.833 -0.854	0.741 -0.825	0.776 -0.803
deep forearm extensors	0.880 -0.897	0.868 -0.904	0.873 -0.905	0.845 -0.897	0.881 -0.906	0.881 -0.900		0.917 -0.935	0.883 -0.910	0.827 -0.882	0.850 -0.872
supinator	0.831 -0.850	0.826 -0.867	0.833 -0.877	0.814 -0.851	0.840 -0.871	0.826 -0.851		0.886 -0.907	0.850 -0.871	0.752 -0.819	0.782 -0.809
pronator teres	0.888 -0.902	0.879 -0.909	0.904 -0.925	0.858 -0.891	0.886 -0.906	0.891 -0.909		0.919 -0.939	0.900 -0.915	0.840 -0.885	0.854 -0.877
flexor carpi radialis and palmaris longus	0.888 -0.902	0.889 -0.916	0.902 -0.922	0.858 -0.899	0.886 -0.912	0.891 -0.906		0.915 -0.939	0.893 -0.914	0.862 -0.891	0.861 -0.880
flexor digitorum superficialis	0.894 -0.907	0.891 -0.923	0.902 -0.926	0.861 -0.904	0.896 -0.919	0.896 -0.911		0.926 -0.943	0.892 -0.915	0.858 -0.888	0.874 -0.892
flexor carpi ulnaris	0.845 -0.864	0.857 -0.901	0.856 -0.890	0.850 -0.882	0.865 -0.896	0.833 -0.859		0.902 -0.924	0.848 -0.874	0.741 -0.829	0.819 -0.846
flexor digitorum profundus	0.922 -0.933	0.924 -0.944	0.922 -0.932	0.899 -0.931	0.929 -0.943	0.923 -0.935		0.947 -0.959	0.924 -0.941	0.870 -0.912	0.907 -0.920

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Canon	GE	Philips	Siemens	Toshiba	Male 18-21 Years	Male Over 21 Years	Female 18-21 years	Female Over 21 years
flexor pollicis longus	0.812-0.836	0.821-0.859	0.819-0.860	0.767-0.838	0.833-0.862	0.811-0.839		0.873-0.894	0.821-0.859	0.748-0.805	0.767-0.800
pronator quadratus	0.772-0.793	0.714-0.788	0.776-0.815	0.712-0.765	0.742-0.792	0.779-0.805		0.805-0.850	0.784-0.813	0.736-0.779	0.711-0.747
vertebrae	0.914-0.927	0.910-0.932	0.764-0.860	0.924-0.954	0.895-0.941	0.918-0.928		0.925-0.944	0.909-0.930	0.918-0.942	0.906-0.924
sternum	0.925-0.933	0.889-0.923	0.893-0.906	0.924-0.943	0.930-0.943	0.920-0.930		0.928-0.938	0.921-0.935	0.908-0.923	0.911-0.929
ribs	0.809-0.828	0.777-0.818	0.844-0.876	0.818-0.854	0.804-0.845	0.795-0.817		0.865-0.892	0.831-0.853	0.753-0.801	0.751-0.779
clavicle	0.895-0.902	0.844-0.889	0.891-0.904	0.894-0.914	0.888-0.900	0.887-0.898		0.912-0.924	0.896-0.908	0.882-0.897	0.865-0.884
humerus	0.963-0.969	0.954-0.968	0.969-0.974	0.963-0.975	0.971-0.978	0.958-0.966		0.981-0.985	0.963-0.973	0.947-0.965	0.951-0.960
ulna	0.898-0.915	0.930-0.951	0.930-0.947	0.919-0.937	0.927-0.945	0.886-0.909		0.942-0.959	0.928-0.941	0.811-0.885	0.860-0.888
radius	0.902-0.918	0.927-0.944	0.930-0.937	0.899-0.929	0.910-0.935	0.900-0.919		0.933-0.957	0.925-0.937	0.835-0.901	0.870-0.897
body from air - core	0.987-0.997	0.995-0.997	0.997-0.998	0.994-0.996	0.997-0.997	0.984-0.997		0.993-0.996	0.994-0.996	0.995-0.997	0.977-0.99
body from air - arms	0.952-0.968	0.960-0.976	0.934-0.982	0.952-0.973	0.969-0.981	0.947-0.968		0.932-0.956	0.951-0.972	0.965-0.987	0.952-0.982
outer abdominal wall	0.977-0.981	0.935-0.986	0.986-0.991	0.977-0.982	0.927-0.993	0.975-0.980		0.977-0.987	0.977-0.982	0.980-0.982	0.951-0.981
abdominal cavity	0.975-0.979	0.953-0.988	0.981-0.987	0.971-0.980	0.945-0.989	0.975-0.979		0.973-0.980	0.978-0.982	0.976-0.981	0.959-0.979
liver	0.976-0.980	0.975-0.982	0.980-0.988	0.977-0.982	0.979-0.983	0.975-0.979		0.975-0.982	0.977-0.981	0.979-0.984	0.974-0.980
kidney	0.972-0.978	0.974-0.983	0.982-0.986	0.965-0.976	0.970-0.981	0.973-0.980		0.972-0.982	0.973-0.982	0.974-0.981	0.968-0.978
Breast tissue	0.858-0.914	0.774-0.960		0.799-0.889	0.892-0.938	0.849-0.922				0.917-0.947	0.838-0.907
thoracic cavity	0.980-0.983	0.979-0.985	0.988-0.991	0.984-0.988	0.979-0.985	0.979-0.982		0.981-0.987	0.980-0.984	0.983-0.986	0.977-0.982

Table 2: The 95% confidence interval for the ROIs in AI settings 1-3 for the absolute volume difference metric.

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Healthy	GE	Healthy	Siemens	Healthy	Male 18-21 Years	Healthy	Female 18-21 years	Healthy
adductor brevis	1.09 -1.74	1.51 -2.29	0 -0.09	0.7 -1.52	0.98 -1.98	1.54 -2.41	0.6 -0.94	1.21 -2	1.19 -1.77	0.09 -2.46	1.28 -2.57
adductor longus	1.5 -2.26	1.52 -2.59	0.08 -2.17	1.08 -2.52	1.93 -3.18	1.48 -2.47	0.62 -1.08	1.37 -2.54	1.69 -2.45	0.19 -2.31	0.88 -2.79
adductor magnus	3.43 -5.45	3.74 -5.62	0.53 -1.84	2.96 -5.6	2.5 -5.58	3.75 -6.24	2.37 -6.3	2.6 -4.76	3.66 -5.42	2.16 -9.98	2.6 -4.36
biceps femoris: long head	1.13 -1.72	2.28 -4.2	0.13 -1.4	1.18 -3.66	1.41 -2.25	1.54 -2.59	0.79 -1.47	1 -2.38	1.52 -2.51	0.34 -2.15	1.21 -3.44
biceps femoris: short head	0.79 -2.28	1.86 -3.38	0 -0.09	1.07 -6.66	0.86 -1.28	1.34 -2.06	0.49 -1.03	1.08 -1.99	1.28 -2.16	-1.03 -6.24	1 -2.11
external rotators	0.72 -0.98	0.73 -1.1	0.16 -0.89	0.47 -0.92	0.7 -1.27	0.81 -1.11	0.37 -0.84	0.76 -1.31	0.8 -1.1	0.33 -0.74	0.43 -0.89
femur	1.58 -5.2	2.07 -3.04	-3.97 -43.01	0.23 -11.13	1.42 -2.27	1.76 -2.55	0.94 -1.42	1.26 -1.99	1.49 -4.51	-0.64 -13.83	1.76 -3.08
fibula	0.52 -0.77	2.37 -4.27	0.06 -0.22	1.18 -3.27	0.45 -0.77	1.09 -1.77	0.28 -0.49	0.57 -1.22	1.07 -2.14	0.29 -0.51	0.75 -1.92
fibulari	1.49 -2.47	2.75 -5.28	0.09 -1.95	1.43 -3.76	1.7 -2.53	1.91 -3.71	1.54 -2.47	1.04 -4.11	2.04 -3.27	1.01 -1.8	1.46 -4.35
flexor digitorum longus	0.65 -1.21	0.97 -1.88	0.04 -0.54	0.66 -1.44	0.48 -0.83	0.91 -1.86	0.39 -0.76	0.65 -2.49	0.71 -1.2	0.41 -0.79	0.65 -1.51
flexor hallucis longus	0.93 -1.57	1.81 -3.52	0.12 -0.46	0.93 -2.27	0.69 -2.83	1.32 -2.23	0.56 -1.38	0.8 -1.48	1.36 -2.51	0.29 -0.88	1.09 -3.2
Gastrocnemius: lateral head	1.35 -2	2.41 -4.07	0 -6.67	1.32 -3.03	1.34 -1.87	1.85 -2.97	0.78 -1.79	1.22 -2.16	1.77 -2.88	0.68 -1.92	1.55 -3.42
Gastrocnemius: medial head	1.18 -3.03	4.05 -9.07	-2.85 -33.17	1.47 -7.55	1.11 -1.68	2.34 -4.27	0.2 -3.12	1 -1.78	2.32 -6.16	0.46 -3.39	2.05 -6
gluteus maximus	4.2 -6.04	8.76 -21.66	0.04 -3.28	0.23 -14.63	4.05 -7.74	7.24 -12.78	1.22 -3.07	4.69 -7.2	5.37 -11.23	0.69 -2.42	6.05 -12.05
gluteus medius	1.27 -2.29	2.22 -3.81	0.02 -0.34	0.98 -2.28	1.46 -2.61	1.93 -3.49	0.56 -1.11	1.54 -3	1.65 -3.12	-0.08 -2.27	1.43 -2.41
gluteus minimus	1 -1.38	1.54 -2.4	0.53 -1.8	0.93 -2.04	1.06 -1.7	1.27 -1.82	0.51 -0.9	0.98 -1.55	1.23 -1.77	0.36 -0.85	1.12 -2.27
gracilis	0.77 -1.3	1.63 -3.19	-0.03 -0.5	0.71 -2.27	0.74 -1.21	1.25 -2.28	0.7 -1.24	0.69 -1.2	1.1 -1.94	0.2 -2.43	0.96 -2.82
iliacus	1.49 -2.18	2.44 -4.44	0.08 -0.82	1.23 -3.38	1.98 -3.37	1.94 -3.13	0.53 -0.98	1.28 -2.42	2.17 -3.2	0.09 -1.93	1.02 -3.8
obturator externus	1.78 -2.53	1.99 -3.08	0.2 -1.5	1.3 -2.34	1.71 -2.93	2.09 -3.09	0.74 -2.69	1.78 -3.55	1.88 -2.72	1 -2.41	1.48 -2.9
obturator internus	0.64 -0.9	1.01 -1.77	-0.04 -0.47	0.82 -1.96	0.74 -1.18	0.72 -1.03	0.35 -0.74	0.7 -1.23	0.85 -1.33	0.24 -0.74	0.47 -1.11
pectineus	1.55 -2.71	1.62 -2.58	-0.05 -0.72	0.66 -1.84	2.47 -5	1.54 -2.8	0.32 -1.02	0.9 -1.87	2.06 -3.6	0.1 -2.31	1.22 -2.25
pelvis	1.66 -2.38	2.53 -3.98	0.45 -1.49	1.25 -2.75	1.47 -2.39	2.49 -3.61	0.59 -1.26	1.16 -2.65	2.21 -3.21	0.7 -2.35	1.75 -3.06

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Healthy	GE	Healthy	Siemens	Healthy	Male 18-21 Years	Healthy	Female 18-21 years	Healthy
phalangeal extensors	1.24 -1.59	1.84 -3	0.18 -0.75	1.28 -2.45	0.92 -1.49	1.68 -2.28	0.86 -1.31	1.19 -1.89	1.49 -2.15	0.83 -1.19	1.25 -2.48
piriformis	1.09 -1.72	1.64 -2.8	-0.1 -1.15	1.05 -3.26	0.87 -1.53	1.4 -2.08	0.82 -1.98	0.8 -2.82	1.15 -1.71	1.04 -1.89	1.16 -2.73
popliteus	0.26 -0.64	0.4 -0.64	-0.01 -0.03	0.29 -0.64	0.27 -0.41	0.31 -0.86	0.21 -0.36	0.34 -0.54	0.3 -0.88	0.15 -0.27	0.26 -0.42
psoas major	2.29 -3.39	2.31 -6.09	0.29 -1.45	1.57 -4.75	2.49 -4.77	2.51 -4.75	0.58 -1.33	2.4 -4.77	2.41 -4.07	0.85 -2.32	1.09 -6.89
quadratus femoris	0.79 -1.1	0.99 -1.81	0.33 -1.19	0.68 -1.21	0.72 -1.22	1.01 -1.59	0.29 -0.58	0.79 -1.31	0.92 -1.24	0.26 -1.34	0.59 -1.95
quadratus lumborum	1.78 -2.25	2.35 -5.13	1.41 -3.92	2.06 -3.75	1.63 -2.45	1.96 -3.71	0.77 -1.58	1.4 -2.34	1.84 -3.47	1.38 -2.5	1.88 -3.85
rectus femoris	1.98 -3.59	3.47 -6.14	-5.19 -20.36	1.29 -5.04	2.41 -3.55	2.83 -4.69	0.8 -1.66	1.59 -4.31	2.37 -4.44	0.41 -4.4	2.71 -5.85
sartorius	1.37 -2.01	2.66 -5.16	0.06 -0.73	1.27 -4.35	1.79 -3.37	1.89 -3.07	0.45 -1	1.05 -3.06	1.85 -3.11	0.19 -1.86	1.83 -4.09
semimembranosus	1.69 -2.93	3.28 -6.43	0.01 -0.71	0.9 -3.64	1.84 -3.49	2.45 -4.58	1.19 -4.41	1.5 -2.62	2.21 -4.07	0.67 -4.61	1.5 -5.07
semitendinosus	1.33 -1.99	2.37 -4.13	0.02 -0.57	0.5 -1.78	1.79 -2.86	1.96 -3.14	0.92 -1.49	0.87 -2.45	1.82 -2.75	0.61 -1.18	1.45 -3.65
soleus	2.23 -3.76	6.99 -12.81	-1.74 -12.49	2.41 -7.78	1.98 -3.6	3.91 -7.1	2.25 -5.58	2.1 -5	3.37 -6.51	0.97 -5.96	3.72 -9.58
tensor fasciae latae	1.06 -1.51	1.77 -3.34	-0.25 -3.22	1.35 -3.02	0.65 -1.38	1.47 -2.33	0.39 -0.88	0.79 -1.59	1.5 -2.37	0.46 -1.39	0.91 -2.44
tibia	1.96 -3.16	2.87 -5.08	-3.1 -10.73	2.1 -4.12	1.4 -4.15	2.43 -3.92	0.79 -1.68	1.66 -3.14	2.33 -4.1	1.24 -2.65	1.96 -5.72
tibialis anterior	0.82 -1.88	1.71 -2.75	-5.14 -17.75	0.68 -1.77	0.84 -1.47	1.32 -1.92	1.11 -1.7	0.83 -1.73	0.95 -2.69	0.71 -1.24	1.25 -2.25
tibialis posterior	1.09 -1.48	1.27 -2.16	0.24 -0.61	0.7 -1.72	1.34 -2.03	1.31 -1.85	0.45 -0.97	1.48 -2.34	1.18 -1.73	0.34 -1.09	0.85 -1.68
vastus intermedius	2.05 -2.73	2.46 -4.12	0.04 -0.54	0.97 -3.11	2.05 -3.35	2.55 -3.48	1.81 -3.41	2.1 -3.36	2.32 -3.22	1.04 -2.55	1.57 -3.49
vastus lateralis	3.72 -5.69	5.57 -9.23	0.19 -1.52	1.97 -6.94	4.54 -6.35	5.03 -7.73	1.3 -7.45	3.39 -7.21	3.79 -5.23	1.78 -9.16	4.81 -8.79
vastus medialis	2.08 -4.39	3.17 -6.29	-3.01 -11.05	1.21 -7.64	2.33 -3.48	2.36 -3.87	-0.26 -13.14	1.64 -3.29	2.04 -3.35	1.43 -12.16	2.2 -5.5
patella	0.114 -0.497	0.196 -0.35	0.682 -7.414	0.02 -0.257	0.124 -0.211	0.191 -0.272	0.075 -0.535	0.111 -0.207	0.127 -0.694	0.037 -0.142	0.141 -0.411
sacrum	7.062 -23.582	22.759 -52.964	0.350 -2.571	1.390 -6.715	13.432 -46.871	15.732 -41.13	3.333 -26.474	1.504 -19.382	18.812 -46.337	1.003 -2.665	8.41 -37.814
rectus abdominis	23.878 -29.782	20.338 -30.031	13.550 -48.782	21.186 -32.654	22.468 -35.392	22.503 -28.963		36.164 -51.063	22.291 -30.999	13.531 -29.988	17.650 -23.422
external oblique	15.215 -19.687	16.880 -27.235	6.826 -27.137	16.913 -32.510	17.435 -28.861	13.823 -18.012		13.095 -21.819	14.891 -20.296	9.409 -35.591	15.099 -22.412
levator scapulae	3.821 -4.680	3.192 -5.241	3.317 -10.693	3.727 -6.261	3.863 -6.427	3.367 -4.160		4.052 -6.234	4.274 -5.610	1.987 -3.846	2.784 -3.883
supraspinatus	3.359 -4.158	3.138 -6.343	1.800 -5.534	4.095 -6.558	3.771 -7.429	2.859 -3.616		3.710 -5.876	3.587 -5.219	1.891 -4.814	2.696 -3.703
trapezius	10.097 -12.988	13.299 -24.974	7.708 -27.781	7.783 -12.809	18.569 -34.071	9.108 -11.419		14.675 -21.746	11.788 -17.728	4.421 -9.797	7.595 -11.879
rhomboid	4.720 -6.129	4.048 -6.206	3.005 -9.366	2.892 -4.685	5.555 -9.293	4.471 -5.979		3.360 -5.603	5.176 -7.017	1.920 -3.645	4.261 -6.647
erector spinae	11.063 -14.247	17.638 -33.596	6.137 -17.135	9.040 -16.114	22.241 -41.834	10.409 -13.379		10.996 -17.512	11.870 -17.849	7.613 -13.137	12.346 -20.578
multifidus	7.874 -13.193	12.656 -36.366	1.900 -71.317	6.058 -22.594	16.377 -46.366	6.228 -10.586		4.846 -11.516	12.224 -24.255	2.453 -7.948	5.916 -14.117
serratus anterior	13.545 -16.978	8.054 -13.165	0.519 -8.964	5.706 -9.665	9.387 -16.213	14.754 -18.646		5.929 -10.457	11.969 -16.861	8.894 -16.159	14.873 -20.140
latissimus dorsi	10.570 -13.519	10.541 -19.420	8.103 -24.238	12.284 -19.722	15.069 -25.751	8.557 -11.445		8.488 -13.324	11.768 -17.023	5.786 -17.145	9.386 -13.591
subscapularis	3.522 -4.496	3.699 -5.317	1.829 -4.609	2.425 -4.048	4.338 -6.525	3.445 -4.518		2.928 -5.093	3.768 -4.883	2.114 -3.468	3.328 -5.062
teres major	1.836 -2.433	1.623 -2.785	1.544 -3.405	1.004 -1.764	1.238 -2.072	1.997 -2.708		1.623 -2.515	2.169 -3.255	0.816 -1.350	1.468 -2.084
infraspinatus and teres minor	3.074 -4.215	2.898 -4.272	1.797 -5.298	3.588 -6.063	2.439 -4.171	2.737 -3.938		3.311 -5.538	3.187 -4.698	1.592 -3.288	2.334 -4.098
pectoralis minor	2.832 -3.720	3.492 -5.298	2.228 -6.124	2.361 -4.073	3.108 -5.171	2.820 -3.827		1.972 -3.583	3.662 -5.230	2.162 -4.381	2.216 -3.078
pectoralis major	7.536 -16.814	11.583 -17.565	-41.991 -172.321	6.945 -12.756	5.102 -44.350	7.435 -11.021		5.827 -9.122	7.362 -24.629	4.316 -7.883	8.474 -14.714
deltoid	5.987 -8.087	7.235 -11.784	3.594 -9.286	5.121 -9.799	5.289 -9.943	6.347 -8.806		6.708 -11.189	8.078 -11.810	2.152 -7.252	3.903 -5.872
triceps brachii	3.525 -6.759	4.560 -8.709	3.297 -6.683	2.441 -3.889	3.356 -8.269	3.948 -8.097		2.272 -6.908	5.152 -7.971	1.016 -3.184	1.980 -8.781
coracobrachialis	1.726 -2.326	1.555 -2.513	1.738 -2.698	1.414 -2.642	1.356 -2.826	1.685 -2.317		1.549 -2.889	1.911 -2.784	0.668 -1.444	1.350 -2.138
biceps brachii	2.969 -4.100	3.580 -5.455	1.464 -4.004	3.103 -5.384	3.256 -5.924	2.829 -4.043		2.870 -4.965	3.500 -5.388	0.770 -2.831	2.587 -3.841
brachialis	2.979 -4.397	2.805 -5.316	4.639 -7.856	2.378 -4.217	3.022 -7.791	2.669 -3.924		1.056 -5.545	3.640 -5.471	1.138 -4.183	2.599 -4.058
brachioradialis	5.130 -6.471	4.605 -8.293	2.039 -4.765	2.956 -6.003	5.049 -8.183	5.381 -6.980		5.672 -8.819	5.002 -6.944	2.564 -6.512	4.238 -6.417

ROI	Descriptive Statistics (DSC) 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Healthy	GE	Healthy	Siemens	Healthy	Male 18-21 Years	Healthy	Female 18-21 years	Healthy
extensor carpi radialis	2.283-3.159	2.324-5.656	2.746-6.688	1.998-4.560	2.409-4.823	2.005-2.956		1.528-2.731	2.548-4.147	1.111-2.222	2.232-3.912
anconeus	1.124-1.562	0.770-1.708	0.637-2.032	0.773-1.735	1.093-1.915	1.032-1.568		1.368-2.504	1.040-1.625	0.391-1.804	0.710-1.284
digit extensors	1.882-2.667	1.155-2.437	1.438-4.755	1.505-3.375	1.481-2.584	1.694-2.664		1.009-2.639	2.047-3.326	1.107-3.162	1.439-2.394
extensor carpi ulnaris	1.357-1.764	0.821-1.881	0.432-2.103	0.884-1.745	1.145-1.991	1.361-1.871		1.087-1.824	1.449-2.078	0.385-2.448	1.046-1.652
deep forearm extensors	1.379-1.808	0.894-1.938	0.487-1.228	1.060-2.103	1.080-1.907	1.377-1.901		0.716-1.528	1.350-1.916	0.945-3.062	1.334-2.066
supinator	0.884-1.154	0.776-1.569	0.815-2.667	0.720-1.232	0.721-1.331	0.873-1.214		0.742-1.094	0.833-1.263	0.223-1.287	0.917-1.412
pronator teres	1.642-2.238	1.573-3.244	0.991-2.371	1.720-3.173	1.558-2.805	1.438-2.166		0.913-1.869	1.842-2.693	1.202-3.706	1.429-2.539
flexor carpi radialis and palmaris longus	2.429-3.321	1.314-2.604	2.111-4.295	1.725-4.437	1.426-3.190	2.363-3.235		2.151-4.092	2.132-3.530	1.475-2.621	1.987-3.156
flexor digitorum superficialis	3.182-4.100	1.073-2.202	1.589-4.840	1.793-3.813	2.243-4.204	3.078-4.141		2.122-3.556	3.429-4.946	1.629-4.795	2.189-3.432
flexor carpi ulnaris	2.773-3.806	1.569-3.320	0.894-7.997	1.413-2.903	1.795-3.323	2.924-4.283		1.476-3.476	3.203-5.026	2.434-4.133	2.018-3.055
flexor digitorum profundus	3.279-4.381	2.926-5.350	1.542-7.712	3.766-7.272	3.981-6.201	2.398-3.311		2.582-4.595	4.016-5.961	1.095-3.620	2.390-3.640
flexor pollicis longus	1.232-1.568	1.003-1.930	0.458-1.711	1.160-1.995	1.190-1.896	1.122-1.526		1.036-1.664	1.267-1.790	0.883-2.151	1.005-1.558
pronator quadratus	0.729-1.022	0.629-1.110	1.114-3.129	0.614-1.494	0.694-1.136	0.595-0.890		0.552-1.273	0.893-1.344	0.270-0.573	0.499-0.810
vertebrae	35.548-53.924	41.949-74.317	167.677-328.471	5.168-22.852	0.544-99.709	37.903-47.806		14.579-29.523	43.239-77.968	30.641-49.443	35.537-49.887
sternum	2.333-3.051	3.047-5.426	0.085-6.579	1.063-3.544	1.253-3.122	2.567-3.357		1.855-3.542	2.927-4.047	1.316-2.846	1.897-3.203
ribs	29.024-33.572	20.805-29.501	6.102-19.254	18.109-24.404	20.010-29.696	31.477-36.609		22.582-33.770	25.854-32.457	26.506-34.630	28.729-35.495
clavicle	0.534-0.688	0.591-1.186	0.229-0.963	0.324-1.027	0.028-1.745	0.568-0.735		0.563-0.979	0.573-0.859	0.364-0.680	0.443-0.670
humerus	2.498-3.527	1.659-6.106	0.694-2.834	1.641-4.226	1.294-2.376	2.775-4.373		1.022-1.634	2.323-4.853	2.733-5.027	2.692-4.052
ulna	1.939-2.682	0.558-1.741	0.562-1.640	0.746-1.418	0.757-2.109	2.276-3.232		0.734-2.253	1.223-1.948	2.014-5.652	2.248-3.487
radius	1.505-2.046	0.793-1.331	0.344-1.371	0.850-2.235	0.963-1.640	1.560-2.171		0.816-1.291	1.273-2.013	1.067-2.962	1.527-2.480
body from air - core	207.244-384.757	106.995-206.879	32.459- 123.942	87.694- 163.101	96.423- 166.274	239.630-471.119		156.056-375.103	180.188-301.831	66.440- 149.328	149.165-537.570
body from air - arms	130.010-198.021	64.650-147.712	48.962-329.982	74.854-165.761	69.941-150.750	130.576-215.971		235.729-448.566	105.542-184.596	25.855-111.108	51.560-118.393
outer abdominal wall	261.758-368.565	7.790-892.968	13.916-114.822	172.644-434.905	256.828-372.548	-44.924-1096.033		180.302-558.447	268.271-418.848	118.037-213.084	115.674-626.266
abdominal cavity	32.99-47.46	-36.09-340.00	5.38-12.56	13.18-41.94	37.26-54.10	-70.21-418.23		27.54-56.05	34.59-56.68	12.11-27.03	-5.82-205.91
liver	16.97-23.19	13.29-32.57	6.10-40.87	14.17-23.08	18.03-26.36	8.31-21.05		14.63-26.36	18.55-30.63	10.46-17.07	13.27-22.04
kidney	3.566-5.784	3.717-7.537	0.697-4.917	2.323-6.041	3.598-5.953	3.357-9.276		2.592-5.928	3.685-7.165	2.099-5.302	3.056-6.340
breast_tissue	28.88-347.08	-17.334-339.999		105.719-232.574	21.160-380.334	9.312-150.361				16.622-77.746	47.296-378.982
thoracic cavity	45.790-66.024	38.193-84.029	50.426-95.380	13.074-47.188	54.118-78.310	22.208-51.752		30.907-78.146	54.057-88.529	10.539-28.431	37.792-61.142

Predetermined Change Control Plan

A Predetermined Change Control Plan (PCCP) has been developed in accordance with the FDA Guidance “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions” (issued December 4, 2024). Modifications to the MuscleView AI/ML models will be made in accordance with the PCCP summarized below:

Modification	Rationale	Modification Protocol	Impact Assessment
#1 - Retraining the AI/ML model for one or more ROIs using additional training data	To improve robustness and generalizability of the AI/ML model by training on additional annotated datasets.	Retraining of the AI/ML model with a mixture of old and new test datasets, followed by performance testing to compare the retrained model to the original version.	<u>Benefit:</u> Improved model generalizability across diverse cases. <u>Risk:</u> Introduction of bias, overfitting <u>Mitigation:</u> Testing data sequestration and testing on new data will ensure proper evaluation and mitigate risks of overfitting.
#2 - Adjustment of AI Model Settings	To improve robustness and generalizability of the AI/ML model used to identify anatomical regions by modifying a predefined set of training hyperparameters and pre/post processing methods during re-training.	Adjustment of preprocessing parameters using existing datasets, followed by performance verification against baseline metrics to ensure output consistency.	<u>Benefit:</u> Improved model generalizability across diverse cases. <u>Risk:</u> Introduction of bias, overfitting <u>Mitigation:</u> Predefined parameter boundaries and comparison to the original metrics mitigate risks of overfitting.
#3 - Addition of data points to the Virtual Control Groups	To improve the statistical significance of the Virtual Control Group (VCG) outputs used to generate scored metrics.	Recalculation of linear regression equations using additional subject data, followed by performance evaluation to ensure equivalent or improved correlation strength.	<u>Benefit:</u> Improved predictive accuracy <u>Risk:</u> Introduction of bias error due to skewed sampling <u>Mitigation:</u> Data collection protocols align with those contained within this submission

Conclusion

The subject device and the predicate device have similar indications for use and are intended for similar applications in musculoskeletal imaging. The technological differences between the devices do not alter the intended use, do not raise new or different questions of safety or effectiveness, and are supported by performance data demonstrating that the subject device is at least as safe and effective as the predicate device.