October 1, 2024

Springbok, Inc.
Scott Magargee
Chief Executive Officer
110 Old Preston Ave
Charlottesville, Virginia 22902

Re: K241331
Trade/Device Name: MuscleView
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: August 19, 2024
Received: August 19, 2024

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.

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241331

Device Name
MuscleView

Indications for Use *(Describe)*
MuscleView is used in adults and pediatrics aged 18 and older to automatically segment muscle and bone structures of the lower extremities from magnetic resonance imaging using a machine learning-based approach. After segmentation, it can provide derived metrics including muscle volume, bone volume, intramuscular fat percentage, and left/right asymmetry.

It is intended to be used by physicians who are trained to interpret MRI images, and serves as an initial method to segment muscle and bone structures from one or more study series. The segmentation results need to be reviewed and edited using appropriate software.

It is intended to only provide the segmentation and derived metrics for muscle and bone structures and cannot serve as direct guidance for diagnosis of any diseases. This device is not intended for use with patients who have tumors in lower limb.

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.

Section 5 – 510(k) Summary K241331

Device Name: MuscleView

Date Summary was Prepared: September 30th, 2024

1. Applicant:

Springbok, Inc.

110 Old Preston Ave

Charlottesville, VA 22902 USA

Contact Name: Scott Magargee – Chief Executive Officer

Phone: 1-215-680-9078

Fax: N/A

E-mail: scott.magargee@springbokanalytics.com

2. Device:

Trade Name: MuscleView

Common Name: MuscleView

Model Number: v1.0

Product Code: LNH

Regulation Description: Magnetic Resonance Diagnostic Device

Regulation Number: 21 CFR 892.1000

Device Class: II

3. Predicate Devices:

Trade Name: AMRA Profiler

Manufacturer: AMRA Medical AB

Address: 68 Southwood Ter SOUTHBURY, CT 06488

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Device Class: Class II

Product Code: LNH

510(k) Number: K173749

510(k) Clearance Date: Dec 06, 2018

4. Device Description

MuscleView is a software only product that uses a machine learning-based approach for the automatic segmentation of musculoskeletal structures from MRI. Based on the segmentation, metrics such as volume and length of the segmented structures are calculated.

The software has the following modules: user management, data management, image processing, AI segmentation & 3D model viewer and metrics calculation. User management involves authentication and access to the software and its results. Data management involves medical image data and its interactions with the system workflow. Image processing involves Pre-processing the DICOM data to create a combined continuous 3D volume(s) of series with similar settings for use in AI segmentation. The segmentation & 3D model viewer module handles training data and algorithms to obtain the pre-trained models and algorithms to update models. Metric calculation module handles the final calculation of relevant metrics.

Input data is preprocessed and prepared for 3D volume segmentation of the musculoskeletal structures. A library of already contoured expert cases is utilized to train the machine learning algorithms, specifically convolutional neural networks (CNNs) perform automated segmentation. This process is in an auxiliary module for AI training.

MuscleView is intended to be used by physicians who are trained to interpret MRI images, and serves as an initial method to segment muscle and bone structures from one or more study series. The segmentation results need to be reviewed and edited using appropriate software. This device is not intended for use with patients who have tumors in lower limb. The currently supported anatomical regions for automatic segmentation are 80 different muscles and bones of the lower extremity. The supported musculoskeletal structures for each region are shown below in **Table 1**.

Upon segmentation, a suite of metrics regarding the segmented 3D volumes is provided. It is intended to only provide the segmentation and derived metrics for muscle and bone structures and cannot serve as direct guidance for diagnosis of any diseases. These metrics include segmentation volume, fat infiltration (if applicable), and limb side asymmetry. The metrics are provided in conjunction with an interactive visualization of the 3D segmentation results.

The software is deployed within a private network on a workstation with an advanced graphic processing unit (GPU) and runs as a service. A web-based interface is used to access the service and manage the data transfer, automatic segmentation, and visualization.

Table 1: List of supported musculoskeletal structures for segmentation. Each ROI is supported for both left and right sides, which are analyzed and validated independently. *Gemelli is a grouping of the superior and inferior gemellus. **Fibulari is a grouping of the fibularis brevis and fibularis longus. ***Phalangeal extensors are a grouping of the extensor digitorum longus, extensor hallucis longus, and fibularis tertius.

Structure Name	Structure Type
Adductor brevis	Muscle
Adductor longus	Muscle
Adductor magnus	Muscle
Biceps femoris (long head)	Muscle
Biceps femoris (short head)	Muscle
Fibulari**	Muscle
Flexor Digitorum Longus	Muscle
Flexor Hallucis Longus	Muscle
Gastrocnemius (lateral head)	Muscle
Gastrocnemius (medial head)	Muscle
Gemelli*	Muscle
Gluteus maximus	Muscle
Gluteus medius	Muscle
Gluteus minimus	Muscle
Gracilis	Muscle

Iliacus	Muscle
Obturator externus	Muscle
Obturator internus	Muscle
Pectineus	Muscle
Phalangeal extensors***	Muscle
Piriformis	Muscle
Popliteus	Muscle
Psoas major	Muscle
Quadratus femoris	Muscle
Quadratus lumborum	Muscle
Rectus femoris	Muscle
Sartorius	Muscle
Semimembranosus	Muscle
Semitendinosus	Muscle
Soleus	Muscle
Tensor fasciae latae	Muscle
Tibialis anterior	Muscle
Tibialis Posterior	Muscle
Vastus intermedius	Muscle
Vastus lateralis	Muscle
Vastus medialis	Muscle
Pelvis	Bone
Femur	Bone
Tibia	Bone
Fibula	Bone

5. Indications for Use Statement

MuscleView is used in adults and pediatric patients aged 18 and older to automatically segment muscle and bone structures of the lower extremities from magnetic resonance imaging using a

machine learning-based approach. After segmentation, it can provide derived metrics including muscle volume, bone volume, intramuscular fat percentage, and left/right asymmetry.

It is intended to be used by physicians who are trained to interpret MRI images, and serves as an initial method to segment muscle and bone structures from one or more study series. The segmentation results need to be reviewed and edited using appropriate software.

It is intended to only provide the segmentation and derived metrics for muscle and bone structures and cannot serve as direct guidance for diagnosis of any diseases. This device is not intended for use with patients who have tumors in lower limb.

6. Summary of Technological Characteristics Comparison

The similarities and differences between the technological characteristics of the two products are shown in **Table 2**. The key difference is the detailed implementation of the automated segmentation algorithms. Testing demonstrates that the differences do not raise new questions of safety or effectiveness.

Table 2. Summary of technological characteristic comparison.

Topic	AMRA Profiler (510k Number: K173749)	MuscleView
Physical Characteristics	A service that is provided with a cloud-based service using an automated image-analysis pipeline (with manual quality control for scan preprocessing and label quality control)	Software package that operates on a virtual machine within off-the-shelf hardware
Computer	Not applicable	PC Compatible
DICOM Standard Compliance	The service processes DICOM compliant image data in accordance with a required MRI protocol.	The software processes DICOM compliant image data
Modalities	MRI	MRI
MRI Parameters of Importance	Collected Series: 3D Dixon water and fat phase. Region of Interest: Lower extremity, Upper body as well Supported Field Strength:	The same except that we support a larger variability in scan properties and coverage

	Direction of Capture: Axial Supported In-Plane Resolution: Supported Slice Spacing: Note: Rigid conformity to MRI protocol is needed.	
User Interface	Concierge Service. Data is provided and analyzed, and results returned	The software is designed for use on a workstation with a web-based user interface. Functionalities are largely the same.
Segmentation Structures	12 individual muscles and 6 muscle groups across the lower and upper extremity and liver	Eighty (8 bones, 72 muscles) individual structures on both the left and right side for the lower extremity focused region.
Segmentation Metrics	Muscle Volume, Fat Fraction	Structure volume, muscle fat infiltration, and derived metrics including asymmetry, muscle length, and cross-sectional area
Overall Segmentation Method	Labeled muscle segmentations automatically generated using non-rigid image registration to atlases utilizing 2D analysis techniques	AI segmentation model-based approach using a library of expert contours for training, MuscleView uses a machine learning-based method to train CNNs from expert contours to perform segmentation on the target images to generate contours
Support of Manual Editing by customer	No	No

7. Performance Data

The safety and performance of MuscleView have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Non-clinical verification and validation test results, including model performance and software usability, established that the device meets its design requirements and intended use, that it is as safe and as effective as the AMRA Profiler (510k Number: K173749), and that no new issues of safety and effectiveness were raised.

Further, during development of the software, potential hazards were controlled by a risk management plan including risk analysis, risk mitigation, verification, and validation.

8. Summary of AI Validation

The artificial intelligence (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 **Table 3** below detailing variation in the data.

Table 3. Summary of AI training and validation dataset's demographics. *Demographic data were not available for some scans.

Factor	Groups	Training data	Validation data
Number of unique scans	n/a	1658	148
Number of unique subjects	n/a	1294	148
Gender	Male (%)	1192*	102
	Female (%)	374*	46
Age*	Mean	29	31.7
	Standard Deviation	13.4	15.5
Ethnicity (based on regional demographics)	% Non-Hispanic White	52	52
	% Hispanic/Latino	18	18
	% Black/African American	14	14
	% Asian	10	10
	% Australian	2	2
	% American Indian / Alaska Native	<1	<1
	% Native Hawaiian / Pacific Islander	<1	<1
	% Australian Aboriginal	<1	<1
	% Other	2	2

MRI Manufacturer	Siemens	680	74
	GE Medical Systems	435	28
	Philips Medical Systems	82	29
	Canon	1	4
	Other (Toshiba) or Unknown	460	13

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.

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%) of datasets in the validation set came from imaging centers and organizations not used in the train datasets (19 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 AI segmentation was validated on the 80 musculoskeletal structures, 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. 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). 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. The 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, 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 4** (DSC) and **Table 5** (VDt).

Table 4: Dice similarity coefficient 95% confidence interval for all 80 musculoskeletal structures across all subgroup analyses.

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 > 21 Years	Male 18-21 Years	Female > 21 years	Female 18-21 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
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

Table 5: Volume difference (ml) 95% confidence interval for all 80 musculoskeletal structures across all subgroup analyses.

ROI	Descriptive Statistics (VDt) ml 95% Confidence Interval										
	Pathology Level Subgroup Analysis		MRI Manufacturer Subgroup Analysis					Age/Biologic Sex Subgroup Analysis			
	Healthy	Patient	Canon	GE	Philips	Siemens	Toshiba	Male > 21 Years	Male 18-21 Years	Female > 21 years	Female 18-21 years
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 -1.28	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
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

9. Substantial Equivalence Conclusion

In conclusion, MuscleView is intended for use in adults and pediatric patients aged 18 and older to quantify automatically segment muscle and bone structures of the lower extremities from magnetic resonance imaging and providing provide derived metrics including muscle volume, bone volume, intramuscular fat percentage, and left/right asymmetry and other derived metrics. It has similar intended use and indications for use statement as the AMRA Profiler (510k Number: K173749). This 510(k) submission includes information on the MuscleView technological characteristics, as well as performance data and verification and validation activities demonstrating that MuscleView is as safe and effective as the AMRA Profiler (510k Number: K173749), and does not raise different questions of safety and effectiveness.