K183012

510(K) SUMMARY

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510(k) submitter:

Elucid Bioimaging, Inc.
225 Main Street, Suite 15
Wenham, MA 01984

Ph. 978-468-0508
Fax: 978-468-0527

Contact person: Andrew J. Buckler, President and CTO, Elucid Bioimaging Inc.

Date prepared:

Device:

Name of device:	vascuCAP™
Common or usual name:	Image processing system
Classification name:	Picture archiving and communications system
Regulatory class:	II
Product code:	LLZ

Predicate device:

Elucid Bioimaging Inc. vascuCAP A.1.1 (K163071)

Device Description:

vascuCAP is an image analysis software package for evaluating CT images of arterial vessels. It allows the processing, review, analysis, communication, and media interchange of multi-dimensional digital images acquired from CT scanners. vascuCAP provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and tissue characteristics. The vascuCAP software application user interface follows typical clinical workflow patterns to process, review, and analyze digital images.

Intended Use:

vascuCAP is a medical image analysis system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired with contrast from CT imaging devices.

vascuCAP is intended to assist trained physicians in the stratification of patients identified to have atherosclerosis. The software post processes images obtained using a multidetector CT. The package provides tools for the measurement and visualization (color coded maps) of arterial vessels.

Clinicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotatable curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Cross-sectional measurements can be obtained using standard vascuCAP software measuring tools. Clinicians can semi-automatically determine contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen

diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit or signal intensity statistics. Clinicians can also manually measure vessel length along the centerline in standard curved MPR views.

The measurements provided by vascuCAP are not intended to provide a diagnosis or clinical recommendations. vascuCAP is intended as a tool to complement standard of care.

Technological Characteristics Comparing to the Predicate:

vascuCAP A.1.2 has all the same technological characteristics and features as vascuCAP A.1, but refines processing algorithms to improve measurement performance.

Performance Data:

Software verification and validation: Software verification and validation consistent with FDA guidance on "General Principles of Software Validation" was conducted, comprising quality planning, requirements analysis, design reviews, software construction, and testing. Verification testing addressed installation and operation qualification, demonstrating that the product meets defined system requirements and features.

Performance testing: Validation testing using phantom and clinical images was conducted to address performance qualification of the subject device under typical operating conditions. Clinical images were evaluated using vascuCAP. Objectives evaluated included calculations of anatomic structure (compared to anthropomorphic phantoms) and calculations of tissue characteristics (compared to expert annotation by board certified pathologists of histopathologic specimens). As a result of this testing, the following analytic performance metrics have been established*:

Structure	**Lumen Area**, tested range 0.3 - 290.1mm^2	*Bias*: 0.81mm^2 [0.3, 1.9], *Intercept*: 0.65mm^2 [-0.6, 0.9], *Slope*: 1.01 [0.9, 1.0], *Quadratic term*: 0.0 [0.0, 0.0], R^2: 0.9987
	Wall Area, tested range 9.4 - 448.6mm^2	*Bias*: 0.50mm^2 [-1.08, 1.29], *Intercept*: -0.59mm^2 [-4.1, 2. 8.0], *Slope*: 1.0 [0.99, 1.04], *Quadratic term*: 0.0 [0.0, 0.0], R^2: 0.9974
	Stenosis**, tested range 33-69%	Vessels ≥5.9mm: *Bias*: 3.7% [1.29, 4.47], *Intercept*: 5.99% [-0.81, 9.93], *Slope*: 0.96 [0.84, 1.1], *Quadratic term*: -0.01 [-0.02, 0.01], R^2: 0.8034
		Vessels <5.9mm: *Bias*: 9.3% [2.14, 12.72], *Intercept*: 34.0% [-2.3, 38.9], *Slope*: 0.55 [0.42, 1.21], *Quadratic term*: 0.001 [-0.02, 0.06], R^2: 0.9549
	Wall Thickness, tested range 1.0 - 9.0mm	*Bias*: 0.5mm [0.3, 0.6], *Intercept*: 0.27mm [-0.1, 0.5], *Slope*: 1.05 [1.01, 1.1], *Quadratic term*: -0.008 [-0.02, 0.01], R^2: 0.9855
	Plaque Burden, tested range 0.4 -1.0 (ratio)	*Bias*: -0.01 [-0.01, .004], *Intercept*: 0.01 [-0.1, 0.04], *Slope*: 0.99 [0.9, 1.1], *Quadratic term*: 0.03 [-0.1, 0.3], R^2: 0.9794
Composition	**Calcified Area**, tested range 0.0 - 51.2mm^2	*Difference*: 0.15mm^2 [-0.5, 0.97], *Intercept*: 0.4mm^2 [-0.02, 1.6], *Slope*: 0.9 [0.6, 1.1], *Quadratic term*: -0.01 [-0.1, 0.04], R^2: 0.875
	LRNC Area, tested range 0.0 - 26.8mm^2	*Difference*: 0.8mm^2 [-0.7, 2.6], *Intercept*: 1.44mm^2 [0.2, 3.4], *Slope*: 0.8 [0.2, 1.1], *Quadratic term*: 0.004 [-0.1, 0.3], R^2: 0.5222
	Matrix Area, tested range 2.6 - 57.1mm^2	*Difference*: -1.6mm^2 [-3.6, 0.32], *Intercept*: 2mm^2 [-3, 5], *Slope*: 0.83 [0.7, 1.0], *Quadratic term*: -0.01 [-0.04, 0.01], R^2: 0.7469

*brief explanatory notes to help interpret the table:

- Range indicates the smallest and largest true value for the measurand tested.

- Each metric is presented as a point estimate followed by a 95% confidence interval (CI). The CI is computed from the statistics of the observed data. It is acknowledged that wide confidence intervals make the established metric quite uncertain, and in general stem from the number of tested data points and metric specific factors.
- Bias for structural measurands and plaque burden are derived from phantom experiments such that ground truth is assessed using micrometer measurements on anthropomorphic objects. Width of confidence intervals follow from the relative difficulty of each phantom geometry and typical variation experienced across clinically-accepted scanning protocols. The mean tested phantom vessel size is 8.7mm [3.9mm, 23.9mm]. For stenosis, the mean tested vessel size of the vessels ≥5.9mm bin was 5.2mm [3.9mm, 5.9mm], and for the vessels <5.9mm bin was 11.9mm [7.9mm, 23.9mm].
- Systematic difference from histopathology for tissue types is estimated relative to pathologist annotation of *ex vivo* tissue specimens with paired CTA such that ground truth is assessed based on expert interpretation that the relevant scientific and clinical community relies upon for diagnosis or other specific categorization of the studied tissue. The mean tested specimen vessel size is 7.9mm [3.6mm, 12.9mm]. The tissue specimens are from the carotid artery, and that as a result, may not account for errors due to motion that may be present in imaging of small vessels depending on the use of ECG gating. Width of confidence interval follows from:
    - agreement of pathologists (three independent annotations were used for these results to account for acknowledged discordance in histopathology interpretation),
    - certainty of positioning of annotated sections into 3D radiology volume (four combinations resulting from two unique positioners crossed with two independent radiologist users were used for these results to account for differences in judgment on where the annotated section data applies within the in vivo volume, blinded to vascuCAP results),
    - relative difficulty of physiologic presentation, and
    - typical variation experienced across clinically-accepted scanning protocols.

**important note regarding stenosis by diameter: given the reliance of stenosis by diameter as being computed from lumen diameters, and the relative difficulty of accurately estimating lumen diameter as the lumens become appreciably smaller than the finite voxel size, the stenosis may be overestimated. This issue is not unique to vascuCAP but rather a known issue for any interpretation of CTA as lumen size decreases. It is important to follow current clinical training to disregard quantitative calculations of stenosis by diameter from CTA when the lumen is not readily visualized and instead for it to be judged qualitatively. Use of such calculations as %stenosis by area, also available from vascuCAP, mitigates but does not completely avoid this issue.

See User Guide for tables of scanner makes, models, and settings used in the testing as well as patient characteristics of the tested population.

Conclusions:

Based on software verification and validation comprising bench and clinical testing under typical operating conditions, Elucid Bioimaging concludes that vascuCAP A.1.2 is as safe and effective as the predicate device for the intended use.