December 21, 2018

Elucid Bioimaging, Inc.
Andrew Buckler
President
225 Main Street, Suite 15
WENHAM, MA 01984

Re: K183012
Trade/Device Name: vascuCAP
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 17, 2018
Received: December 17, 2018

Dear Andrew Buckler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183012

Device Name
vascuCAP

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K183012

510(K) SUMMARY

510(k) SUMMARY

510(k) submitter:

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Wenham, MA 01984

Ph. 978-468-0508
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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.