Elucid Bioimaging Inc.
℅ Doug Shufelt
Director of QA and RA
2 Park Plaza, Suite 700
BOSTON MA 02116

Re: K221463
Trade/Device Name: ElucidVivo A.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 13, 2022
Received: May 19, 2022

June 17, 2022

Dear Doug Shufelt:

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/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 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 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221463

Device Name
ElucidVivo™ A.3

Indications for Use *(Describe)*
ElucidVivo 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. ElucidVivo 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 ElucidVivo 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 ElucidVivo are not intended to provide a diagnosis or clinical recommendations. ElucidVivo 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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ElucidVivo™ A.3 Special 510(k) Summary

510(k) submitter:

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Contact person: Doug Shufelt, Director of QA and RA, Elucid

Date prepared: 16 May 2022

Device:

Name of device:	ElucidVivo™ A.3
Common or usual name:	Image processing system
Classification name:	Medical image management and processing system
Regulatory class:	II
Product code:	LLZ
Classification Regulation:	21 C.F.R. § 892.2050

Predicate device:

Manufacturer	Device Name	K-Number
Elucid Bioimaging Inc.	vascuCAP A.1.2	K183012

Note: The device name was rebranded to ElucidVivo from its predicate device, vascuCAP for business purposes. There are no changes to the indications of use.

Device Description:

ElucidVivo 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. ElucidVivo provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The ElucidVivo software application user interface follows typical clinical workflow patterns to process, review, and analyze digital images.

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Intended Use

ElucidVivo 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. ElucidVivo 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 ElucidVivo 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 ElucidVivo are not intended to provide a diagnosis or clinical recommendations. ElucidVivo is intended as a tool to complement standard of care.

Technological Characteristics Comparing to the Predicate:

ElucidVivo™ A.3 has the same intended use as ElucidVivo A.1.2 using the same technological characteristics and features as ElucidVivo A.1.2 but improves measurement performance for Lipid Rich Necrotic Core (LRNC), matrix (MATX) and calcifications (CALC). The algorithm is performing the same measurements as the predicate using the same technology with performance results as stated based on the device changes. This was done:

- By taking into consideration different energy levels and calibrating kVp for measurement of plaque components (calcium, matrix and lipid rich necrotic core).
- In the predicate device we have used H&E stain which is commonly used in vascular pathology. Since the predicate device was released, scholarship in the field of pathology has increasingly recognized that using MOVAT stain provides additional fidelity for delineation of LRNC relative to other tissues such as IPH, and hence adopted it for the subject device.

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.

The same test protocols (3-DC-1-PM-01 ElucidVivo Verification & Validation Plan) were used in the predicate and subject devices. The two differences between performance tables of A.3 compared to predicate A.1.2 are as follows:

- Whereas the primary performance metrics of bias, slope and intercept remain the same, the secondary metrics used in A.1.2 of quadratic term and R2 are replaced by terms more in conformance with best practice metrology metrics of RMSE and wSD (noting that the term 'difference' is used instead of 'bias' for the tissue composition as also done in the predicate device, to reflect the histology ground truth basis).
- The composition performance reflects the test results based on the improved kVp calibration and use of MOVAT stain (as explained in the executive summary of the application).
- Independent test data that had been blinded during the prior A.1.2 and preserved this release, has been used to avoid inadvertent bias associated with reuse of test data which is the reason why we see changes to the tested range in composition performance data compared to predicate device, vascuCAP A.1.2.
- The stenosis performance results (Section 21.4) for ElucidVivo A.3 has been quoted as the aggregate of two bins compared to the predicate, vascuCAP A.1.2.

Performance testing: Validation testing using phantom and clinical images was conducted to address performance qualification of the subject device under typical operating conditions which is similar to the protocols used for testing performance of predicate device. Clinical images were evaluated using ElucidVivo. Objectives evaluated included calculations of anatomic structure (interchangeability with manual measurements as well as inter- and intra-reader variability) and calculations of tissue characteristics (compared to histopathologic specimens representing ground truth as well inter- and intra-reader variability). As a result of this testing, the following analytic performance metrics have been established *:

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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], *RMSE:* 2.50 [1.30,2.80], *wSD:* 2.30 [1.20,2.60]
	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], *RMSE: 4.10* [2.60,6.60], *wSD: 3.90* [2.40,6.30]
	Stenosis, tested range 33-69%	*Bias*: 6.10 [3.10,8.90], *Slope*: 0.97 [0.83,1.20], *Intercept*: 7.90 [-4.60,15.00], *RMSE:* 7.00 [3.60,11.00], *wSD:* 6.20 [3.20,9.60]
	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], *RMSE: 0.*24 [0.17,0.31], *wSD:* 0.21 [0.15,0.28]
	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], *RMSE:* 0.018 [0.012,0.038], *wSD:* 0.017 [0.012,0.036]
Composition	**Calcified Area (mm^2):** Tested range: 0-14	*Difference*: -0.06 [-0.09,-0.03], *Slope*: 0.99 [0.91,1.07], *Intercept*: -0.04 [-0.08,0.01], *RMSE:* 1.46 [1.32,1.59], *wSD:* 1.43 [1.31,1.56]
	LRNC Area (mm^2): Tested range: 0-10	*Difference*: 0.15 [0.10,0.20], *Slope*: 0.92 [0.87,0.96], *Intercept*: 0.34 [0.27,0.42], *RMSE:* 2.79 [2.70,2.89], *wSD:* 2.76 [2.67,2.85]
	Matrix Area (mm^2): Tested range: 4-52	*Difference*: 0.02 [-0.22,0.26], *Slope*: 0.91 [0.88,0.94], *Intercept*: 1.34 [1.00,1.67], *RMSE:* 3.77 [3.64,3.89], *wSD:* 3.58 [3.46,3.69]

*brief explanatory notes to help interpret the table:

1. Tested range indicates the smallest and largest true value for the measurand tested characterize the difference profile over the tested range.
2. 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]. Width of confidence interval follows from:
    1. agreement of pathologists (three independent annotations were used for these results to account for acknowledged discordance in histopathology interpretation),

2. 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 ElucidVivo results),
3. relative difficulty of physiologic presentation, and
4. 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 ElucidVivo 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 ElucidVivo, mitigates but does not completely avoid this issue.

Conclusions:

Based on software verification and validation comprising bench and clinical testing under typical operating conditions, Elucid Bioimaging concludes that ElucidVivo™ A.3 is as safe and effective as the predicate device for the intended use.