DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2017

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

Re: K163071
Trade/Device Name: vascuCAP
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 18, 2017
Received: May 19, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163071

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 ≥ 4.5mm in diameter.
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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510(K) SUMMARY

510(k) SUMMARY

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 CEO, 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:

Vital Images, Inc. Vitrea Version 4.0 (K071331)

Device Description:

vascuCAP is an image analysis software package for evaluating CT images of arterial vessels ≥ 4.5mm in diameter. 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 ≥ 4.5mm in diameter.

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:

The vascuCAP has all the same technological characteristics and features as the Vitrea, Version 4.0, but the predicate Vitrea device has broader applications and, therefore, additional features. Specifically, vascuCAP processes and reviews, and analyzes images from CT scanners and not other modalities, and vascuCAP images arterial vessels ≥ 4.5mm in diameter, whereas the Vitrea images various anatomies including vessels. Additionally, vascuCAP does not have a post-processing application for assessment of the heart and is not intended for use with the St. Jude Ensite system.

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. Validation testing using phantom and clinical images was conducted to address performance qualification of the subject device under typical operating conditions.

Conclusions:

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