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.