September 12, 2024

Elucid Bioimaging, Inc.
Hiral Vora
Lead Quality and Regulatory Affairs Specialist
399 Boylston Street
Suite 400
Boston, MA 02116

Re: K241524
Trade/Device Name: Elucid PlaqueIQ
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2024
Received: August 5, 2024

Dear Hiral Vora:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241524

Device Name
Elucid PlaqueIQ

Indications for Use *(Describe)*
Elucid PlaqueIQ is intended to support qualified clinicians in the non-invasive evaluation and assessment of plaque quantification and morphology (e.g., atherosclerosis) from previously acquired CT angiography. The results are intended to support qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.

Prescription use only.

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

K241524

Submitter Information

Submitter / Manufacturer Name	Elucid Bioimaging, Inc. 399 Boylston Street, Suite 400, Boston, MA 02116
Primary Correspondent & Contact Information	Hiral Vora Lead Quality and Regulatory Affairs Specialist Email ID: hiral.vora@elucid.com
Secondary Correspondent & Contact Information	Windi Hary SVP, Quality and Regulatory Email ID: windi.hary@elucid.com
Date Prepared	11 September 2024

Device Identification

Proprietary Name:	Elucid PlaqueIQ
Device Classification Name:	System, Image Processing, Radiological
Regulation Description:	Medical image management and processing system
Regulation Number:	892.2050
Device Class	Class II
Product Code:	LLZ

Predicates

Proprietary Name:	Autoplaque add-on ORS Visual
Device Classification Name:	System, Image Processing, Radiological
Regulation Description:	Medical image management and processing system
510(k) Number:	K122429
Regulation Number:	892.2050
Device Class	Class II
Product Code:	LLZ

Reference Device

Proprietary Name:	vascuCAP A.1.2
Device Classification Name:	System, Image Processing, Radiological

Regulation Description:	Medical image management and processing system
510(k) Number:	K183012
Regulation Number:	892.2050
Device Class	Class II
Product Code:	LLZ

Device Description

Elucid PlaqueIQ is an image analysis application for evaluating CT angiography images of arterial vessels. Elucid PlaqueIQ provides multi-dimensional visualization to aid clinicians in their analysis of plaque anatomy and pathology (e.g., atherosclerosis). Elucid PlaqueIQ supports physician review and interrogation of the Elucid conducted segmentation to inform their clinical interpretation of the Elucid PlaqueIQ Analysis.

Indications of Use

Elucid PlaqueIQ is intended to support qualified clinicians in the non-invasive evaluation and assessment of plaque quantification and morphology (e.g., atherosclerosis) from previously acquired CT angiography. The results are intended to support qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.
Prescription use only.

Indications of Use comparison discussion

Autoplaque is an on-prem desktop plaque analysis application, where physicians generate segmentations and apply plaque algorithms for quantification. The results are then presented to the physician. Elucid PlaqueIQ is a cloud-based application, where Elucid Analysts generate the segmentations (as a service) and apply plaque algorithms for quantification. The results are then provided to the physician. Elucid monitors their analyst/product performance to ensure repeatability and reproducibility of the segmentations and plaque outputs. Therefore, we feel the differences in indications do not present any additional concerns of safety or effectiveness.

Technological Characteristic Comparison

Elucid PlaqueIQ is an image analysis software that is used to process, review, and analyze CT images. It has the same technological characteristics as the predicate device. It does not come in contact with the patient, nor does it control any life-sustaining devices. It provides physicians with a tool that aids with interpretation of CT images and information displayed. Even though there are some technological differences between subject device and predicate device in terms of computer operating system, and provision of product as stand-alone device; these differences do not impact the safety and effectiveness of the product. Additionally, these differences are addressed through software verification and validation.

Predicate Device Comparison

Comparison Criteria	Elucid PlaqueIQ (B.1P) (Subject Device)	Autoplaque add-on ORS Visual (Primary Predicate)	vascuCAP A.1.2 (Reference Device)	Comparison Assessment
510(k)	To be assigned	K1224291	K183012	-
Manufacturer	Elucid Bioimaging, Inc.	Object Research Systems (ORS) inc.	Elucid Bioimaging, Inc.	-
Product Code	LLZ	LLZ	LLZ	Same as predicate
Regulation Number	892.2050	892.2050	892.2050	Same as predicate
Regulation Description	Medical image management and processing system	Medical image management and processing system	Medical image management and processing system	Same as predicate
Device Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	Same as predicate
Device Class	Class II	Class II	Class II	Same as predicate
Data Source (input)	CT	CT	CT	Same as predicate
Output	Graphics and text results of arterial anatomy that can be accessed by end users/physicians using a device with internet connectivity	Graphic and text results of coronary anatomy that can be accessed by end users/physicians using the product.	Graphics and text results of arterial anatomy that can be accessed by end users/physicians using a device with internet connectivity	Similar to predicate
Physical Characteristics	• Cloud-based segmentation and analysis as service • DICOM compatible	• Software installed and used by end-user • DICOM compatible	• Software installed and used by end-user • DICOM compatible	Similar to predicate
Safety	Clinician review and assessment of analysis prior to use as	Clinician editable, review, and assessment of analysis	Clinician editable, review and assessment of analysis prior to use	Similar to predicate except clinicians cannot edit the

	supplemental diagnostic aid	prior to use as supplemental diagnostic aid	as supplemental diagnostic aid	analysis; however, they can request rework of the analysis.
Computer Operating System	Windows OS and Mac OS	Windows OS	Windows OS and Mac OS	Similar to predicate except subject device can be operated on Mac OS system as well
2D Imaging	Review of arterial vessels in 2D MPR, curved MPR, and straightened view.	Review of coronary vessels in 2D MPR, curved MPR, and straightened view.	Review of arterial vessels in 2D MPR, curved MPR, and straightened view.	Similar to predicate
3D Imaging	Review of structures in 3D	Review of structures in 3D	Review of structures in 3D	Same as predicate
Maximum intensity projection (MIP)	MIP with interactive control	MIP with interactive control	MIP with interactive control	Same as predicate
Multiplanar reformatting (MPR)	MPR with oblique slicing and variable slab thickness	MPR with oblique slicing and variable slab thickness	MPR with oblique slicing and variable slab thickness	Same as predicate

Summary of Tests

The software was designed, developed, verified and validated for performance per the written procedures. Verification, validation and usability testing data demonstrated that the device meets all of its specifications demonstrating substantial equivalence to the predicate device.

Any risks identified during product development were controlled and mitigated by a risk management plan including risk analysis, risk evaluation, risk control and evaluation of residual risks.

The following non-clinical tests were performed:

1. Verification testing verified the overall functionality and repeatability conforming to the software specifications.
2. Validation testing confirmed that the performance of the software met the pre-defined acceptance criteria.
3. Usability testing was conducted with intended users of the device and ensures the acceptability of the device.

The nonclinical verification and validation test results established that the device meets its design requirements and intended use.

Conclusion

Based on the intended use, technological characteristic, summary of tests and comparison to the predicate, Elucid PlaqueIQ raises no new questions of safety and effectiveness as compared to the predicate and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.