Navier Medical
Aastha Chaudhary
Quality and Regulatory Manager
Level 13, Office 1
256 Adelaide Tce
Perth, WA 6000
Australia

June 16, 2025

Re: K244012
Trade/Device Name: Mosaic (V1.0.1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 16, 2025
Received: May 19, 2025

Dear Aastha Chaudhary:

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).

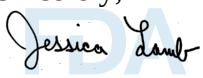
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Jessica Lamb
Assistant Director
Imaging Software Team
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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.

Submission Number *(if known)*

K244012

Device Name

Mosaic (V1.0.1)

Indications for Use *(Describe)*

Mosaic V1.0.1 is a medical image analysis system that allows the viewing, processing, and analysis of multi-dimensional digital images acquired with contrast from CT imaging devices.

Mosaic V1.0.1 is intended to assist trained medical professionals in the stratification of patients suspected or identified to have atherosclerosis as well as stratification of patients suspected or identified to have aneurysmal disease of the aorta or carotid, iliac, femoral and popliteal arteries.

The software enables post processing of images obtained using a multidetector CT and provides tools for the measurement and visualisation of arterial vessels and any disease present, including editing of contrasted lumen and artery boundaries.

Any processed artery can be selected to view: the vessel in 3D; color-coded interactive data maps displayed on the 3D vessel; curved, straightened and cross-sectional MPR views of the vessel; and quantitative data from regions of interest. Data includes standard 2D distance measurements as well as stenosis, Hounsfield unit statistics, and tissue volumes.

Typical users of Mosaic V1.0.1 outputs are trained medical professionals, including radiologists and clinicians. Typical operators of Mosaic V1.0.1 are those suitably trained in the use of the software.

Mosaic V1.0.1 is intended to complement standard of care but is not intended to provide a diagnosis or clinical recommendation.

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.

Mosaic V1.0.1 510(k) Summary Statement

1 Company and Product Details

1.1 510(k) Submitter

Company Name	Navier Medical Ltd
Address	Office 1, Level 13, 256 Adelaide Terrace, Perth WA 6000, Australia
Phone Number	+61 0450 215 141
Contact Person	Aastha Chaudhary, QA and RA Manager
Date Prepared	16-June-2025

1.2 Subject Device

Manufacturer Name	Navier Medical Ltd
Device Name	Mosaic V1.0.1
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

1.3 Predicate Device

Manufacturer Name	Elucid Bioimaging Inc.
Device Name	ElucidVivo A.3
510(k) reference	K221463
Classification Name	Medical image management and processing system
Regulatory Class	II
Product Code	LLZ
Classification Regulation	21 C.F.R. § 892.2050

No reference devices were used in this submission.

2 Device Description

Mosaic V1.0.1 is a post-processing tool used to analyse arterial diseases. It reads in computed tomography angiography (CTA) scans and users can process the scans to aid clinicians in their analysis of anatomy and pathology. Processing CTA with Mosaic enables the creation of vessel centrelines from which measurements and image reformatting is possible. The outputs of the software include visual images, measures of diameter, distance, volume, including plaque volumes, positive remodelling of the arterial wall, and stenosis. These measurements are based on user segmentation. Outputs from Mosaic, including the saved analysis file and PDF report, can be used to assist with the decision-making process and clinical management of the patient, but Mosaic is not intended to be used as a sole source of clinical data to determine diagnosis and/or treatment pathways.

3 Indications for Use

Mosaic V1.0.1 is a medical image analysis system that allows the viewing, processing, and analysis of multi-dimensional digital images acquired with contrast from CT imaging devices.

Mosaic V1.0.1 is intended to assist trained medical professionals in the stratification of patients suspected or identified to have atherosclerosis as well as stratification of patients suspected or identified to have aneurysmal disease of the aorta or carotid, iliac, femoral and popliteal arteries.

The software enables post processing of images obtained using a multidetector CT and provides tools for the measurement and visualisation of arterial vessels and any disease present, including editing of contrasted lumen and artery boundaries.

Any processed artery can be selected to view: the vessel in 3D; color-coded interactive data maps displayed on the 3D vessel; curved, straightened and cross-sectional MPR views of the vessel; and quantitative data from regions of interest. Data includes standard 2D distance measurements as well as stenosis, Hounsfield unit statistics, and tissue volumes.

Typical users of Mosaic V1.0.1 outputs are trained medical professionals, including radiologists and clinicians. Typical operators of Mosaic V1.0.1 are those suitably trained in the use of the software.

Mosaic V1.0.1 is intended to complement standard of care but is not intended to provide a diagnosis or clinical recommendation.

4 Intended Use

Mosaic V1.0.1 is intended to assist trained medical professionals in the stratification of patients suspected or identified to have atherosclerosis as well as stratification of patients suspected or identified to have aneurysmal disease of the aorta or carotid, iliac, femoral and popliteal arteries. The software post processes images obtained using a multidetector CT and provides tools for the measurement and visualisation of arterial vessels and any disease present.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations.

5 Technological Characteristics Compared to the Predicate

Mosaic V1.0.1 has all the same technological characteristics and features as ElucidVivo.

Characteristic	Mosaic V1.0.1 (Subject)	ElucidVivo™ A.3 (Predicate)	Comparison Assessment
Computer Operating System	Windows OS	Windows OS and Mac OS	Similar to predicate.
Image Input Format	DICOM	DICOM	Same as predicate.
Image Acquisition	CT	CT	Same as predicate.
Hounsfield Unit (HU)-based Segmentation	YES	YES	Same as predicate.
2D Imaging	YES	YES	Same as predicate.
3D Imaging	YES	YES	Same as predicate.
Multiplanar Reformatting (MPR)	YES	YES	Same as predicate.
2D Measurements	YES	YES	Same as predicate.
Vessel Stenosis	YES	YES	Same as predicate.
Volumetric Measurements	YES	YES	Same as predicate.
Features of Arterial Disease (based on HU)	Calcified tissue (> 350 HU) Low-attenuating plaque (Adaptive algorithm) Custom	Calcified tissue (>250 HU) Low-attenuating plaque (called Lipid Rich Necrotic Core; < 45 HU)	Similar to predicate.

Characteristic	Mosaic V1.0.1 (Subject)	ElucidVivo™ A.3 (Predicate)	Comparison Assessment
		Matrix (45-250 HU)	
Positive Remodeling Index	YES	YES	Same as predicate.
Reporting (PDF)	YES	YES	Same as predicate.

6 Performance Data

Software verification and validation activities were consistent with FDA guidance on "General Principles of Software Validation", "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices." Verification testing demonstrated 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 with 0.54 x 0.54 mm pixel resolution were evaluated using Mosaic relative to ground truth measurements. Measurements included calculations of vessel diameter, length, tissue volumes, stenosis and positive remodelling index over ranges that reflect the intended use of the software. The following performance metrics (mean [95% CI] were established:

- Diameter was tested over 2.0 mm to 60.0 mm with bias of ranging from 0.015 [-0.039, 0.070] to 0.100 [-0.121, 0.123] and RMSE from 0.079 [0.044, 0.113] to 0.239 [0.142, 0.335]. Bias and RMSE are in mm.
- Tissue volume was tested over 0.65 cm^3 to 226.19 cm^3 with bias ranging from -0.012 [-0.032, 0.009] to -3.120 [-4.819, -1.420] and RMSE from 0.039 [0.022, 0.055] to 4.331 [2.995, 5.666]. Bias and RMSE are in cm^3.
- Stenosis was tested over 33% to 85% with bias ranging from 0.2 [-1.0, 1.5] to 7.8 [4.5, 11.0] and RMSE from 2.0 [1.0, 3.1] to 9.3 [2.4, 16.3]. Bias and RMSE are in %.
- Positive remodelling index was tested from 1.17 to 1.57 with bias ranging from -0.010 [-0.015, -0.005] to -0.073 [-0.102, -0.044] and RMSE from 0.013 [0.009, 0.017] to 0.089 [0.066, 0.112]. Bias and RMSE are unitless.

Measurements from Mosaic were shown to be substantially equivalent to ElucidVivo.

7 Cybersecurity

Navier Medical has implemented security features for device and data protection. Cybersecurity requirements, risk analysis, and mitigation were addressed in accordance with FDA guidance, "Content of Premarket Submission for Management of Cybersecurity in Medical Devices".

8 Conclusions

Based on software verification and validation comprising testing under typical operating conditions, Navier Medical concludes that Mosaic is as safe and effective as the predicate device for the intended use. Thus, Mosaic V1.0.1 is substantially equivalent to the predicate device.

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