



September 10, 2025

Angiowave Imaging, Inc.
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
Naples, Florida 34114

Re: K244002

Trade/Device Name: AngioWaveNet
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, OWB
Dated: August 5, 2025
Received: August 5, 2025

Dear Daniel Kamm:

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

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

Enclosure

Indications for Use

Submission Number (if known)

K244002

Device Name

AngioWaveNet

Indications for Use (Describe)

AngioWaveNet is indicated for use by qualified physicians or under their supervision to aid in the analysis and interpretation of X-ray coronary angiographic cines. AngioWaveNet is intended for use in adults during X-ray coronary angiographic imaging procedures as a clinically useful complement to the viewing of standard angiographic cines acquired during diagnostic coronary angiography procedures. AngioWaveNet software is intended for use to enhance the visibility of blood vessels, vascular structures, and related anatomical features within angiographic images, which may be clinically useful to the treating physician

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary, 510(k) K244002

Submitter: AngioWave Imaging, Inc

82 Alden Road, Concord, MA 01742

Submitted by: Aram T. Salzman, CEO, Co-Founder

Telephone: 1-617-901-8989

Date Prepared: August 4, 2025

1. Identification of the Device:

Trade/Device Names: AngioWaveNet

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical image management and processing system

Regulatory Class: II

Product Code: QIH, Secondary Product Code OWB

2. Equivalent legally marketed devices: K212074

Trade/Device Name: ClariCT.AI

Manufacturer: ClariPi USA Inc.

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical image management and processing system

Regulatory Class: II

Product Code: LLZ

3. Reference Device:

K232526

Trade/Device Name: Canon XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5

Manufacturer: Canon Medical Systems Corporation

Regulation Number: 21 CFR 892.1650

Regulation Name: Image-intensified fluoroscopic x-ray system

Regulatory Class: II

Product Code: OWB, JAA

4. Indications for Use: AngioWaveNet is indicated for use by qualified physicians or under their supervision to aid in the analysis and interpretation of X-ray coronary angiographic cines. AngioWaveNet is intended for use in adults during X-ray coronary angiographic imaging procedures as a clinically useful complement to the viewing of standard angiographic cines acquired during diagnostic coronary angiography procedures. AngioWaveNet software is intended for use to enhance the visibility of blood vessels, vascular structures, and related anatomical features within angiographic images, which may be clinically useful to the treating physician

5. Description of the Device: AngioWaveNet spatio-temporal enhancement processing (STEP) is an artificial Intelligence (AI) and machine learning (ML) system designed to enhance the visibility of blood vessels in angiograms using the unique spatial and temporal information contained in the frames of angiographic cines. The Angiowave STEP method employs a neural network architecture in the form of an encoder-decoder, which sequentially takes multiple contiguous frames of an angiogram as input and uses this information to provide enhanced visualization of vessels in the central frame. Angiowave has developed a novel and versatile implementation of its processing in a DICOM node, which has the benefit of no additional on-premises hardware. In addition to the cine processing, the DICOM node handles other logistical tasks such as anonymization, image storage and retrieval (e.g. to/from a cloud location),

communication and interoperability, data integrity and security, DICOM conformance, and data archiving and management. This full implementation utilizing a cloud location for processor intensive tasks is termed AngioWaveNet. The AI/ML model at the heart of STEP was trained on a comprehensive dataset of 300 anonymized angiograms, averaging 70 frames each, provided by a large non-profit healthcare organization that operates in Maryland and the Washington, D.C. region. The dataset spanned a range of clinical and demographic characteristics presenting to the catheterization laboratory and was acquired from 2003 to 2016 using Philips Allura Xper systems. The dataset was randomly sampled from a large clinical study population, whose baseline patient characteristics have been published and were consistent with a typical coronary catheterization lab population.

6. Safety and Effectiveness, comparison to predicate device. This device has the similar indications for use and similar technological characteristics as the predicate device.

7. Substantial Equivalence Chart:

	Subject Device	Predicate Device	Reference Device
Device Name	AngioWaveNet	ClariCT.AI K212074 ClariPi USA Inc.	Canon XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5 K232526 Canon Medical Systems
Product Code	Primary QIH. Secondary OWB	LLZ	OWB, JAA
Regulation	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1650
Indications for Use	AngioWaveNet is indicated for use by qualified physicians or under their supervision to aid in the analysis and interpretation of X-ray coronary angiographic cines. AngioWaveNet is intended for use in adults during X-ray coronary angiographic imaging procedures as a clinically useful complement to the viewing of standard angiographic cines acquired during diagnostic coronary angiography procedures. AngioWaveNet software is intended for use to enhance the visibility of blood vessels, vascular structures, and related anatomical features within angiographic images, which may be clinically useful to the treating physician	ClariCT.AI, is a software device intended for networking, communication processing and enhancement of CT images in DICOM format regardless of the manufacturer of CT scanner or model.	The Angio Workstation (XIDF-AWS801) is used in combination with an interventional angiography system (Alphenix series systems, Infinix-i series systems and INFX series systems) to provide 2D and 3D imaging of selective catheter angiography procedures for the whole body (includes heart, chest, abdomen, brain and extremity). When XIDF-AWS801 is combined with Dose Tracking System (DTS), DTS is used with selective catheter angiography procedures for the heart, chest, abdomen, pelvis and brain.
Intended User	Interventional cardiologists and related specialists	Radiologists and specialists	Interventional cardiologists and related specialists
Modality Support	Fluoroscopic angiography	CT	Fluoroscopic angiography

	Subject Device	Predicate Device	Reference Device
System Compatibility	All X-ray angiography systems exporting to XA DICOM modality	All CT Scanners	Canon Alphenix series systems Infinix-i series systems INFX series systems
Image processing Method	Pre-trained deep-learning models	Pre-trained deep learning models	Pre-trained deep-learning models
Supported Image Format	DICOM ● 512x512 8 or 16 bits ● 1024x1024 8 or 16 bits	DICOM 512x512x8 bits	DICOM 512x512x8 bits
Components and Hardware Requirements	On-site client: Intel Quad Core i7-4770 3.4GHz minimum ● 32GB Ram ● Windows 10 or 11 Professional	Windows Operating System, PC Hardware, CUDA supported graphics card or equivalent	PC Hardware with GPU

8. Summary of non-clinical testing: We performed software validation and risk management for the software. The following FDA guidances were employed in those activities:

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

Software documentation was provided for a BASIC level as described in the FDA guidance. That included a Documentation Level Evaluation, Software Description, Risk Management File, Software Requirements Specification, System and Software Architecture Diagram, Software Design Specification (SDS) Software Development, Configuration Management, and Maintenance Practices, Software Testing as part of Verification and Validation, Software Version History, and finally, Unresolved Software Anomalies.

For cybersecurity we provided a Cybersecurity Risk Management Report, the Threat Model, the Cybersecurity Risk Assessment, the Software Bill of Materials (SBOM), the Assessment of Unresolved Anomalies, Cybersecurity Metrics, Cybersecurity Controls, Architecture Views, Cybersecurity Testing, Cybersecurity Labeling, Cybersecurity Management Plan, and Interoperability information.

The software complies with NEMA PS 3.1 - 3.20 2024a Digital Imaging and Communications in Medicine (DICOM) Set.

9. Summary of clinical testing: The AngioWaveNet Task-Based Reader Study, conducted in July and August of 2025, comprehensively evaluated the performance of advanced angiographic image processing software across 31 patient cases selected from a large angiographic database. 50 sequential cases were drawn from the database, and the first 31 meeting inclusion criteria were successfully processed and analyzed. Utilizing a methodology developed under a prescribed protocol, the study was performed by three experienced interventional cardiologists who assessed the software's clinical decision impact on a comprehensive list of angiographic pathologic determination tasks and its ability to improve ease of visualization of diagnostic coronary angiograms. AngioWaveNet version 1.0.0 demonstrated a 100% processing success rate, with all analyzed cases meeting predefined patient-level success criteria. Further details about the testing:

i. Summary Test Statistics or Acceptance Criteria:

The study achieved all pass criteria, with all 31 patients showing neutral or positive clinical decision impact (mean Likert score 3.23, range 3.12–3.44 across three readers). Ease of visualization improved in 99.4% of tasks, with 0% unresolved false positives/negatives for most readers

ii. Number of Individual Patients, Images Collected From

Angiographic cines were collected from 31 individual patients, drawn from the Corewell Angiographic database.

iii. Number of Samples and Relationship to Patients

The study analyzed 97 angiograms (cines) across 31 patients, with each patient contributing 3–4 cines (mean 3.13 cines/patient). A total of 169 vessels were assessed, with 3,211 tasks (detection, localization, quantification, characterization) performed across all cines.

iv. Demographic Distribution (Gender, Age, Ethnicity)

The patient cohort (n=31) had a mean age of 67.5 years, with 58.1% male and 41.9% female. Ethnicity distribution was 90.3% White, 6.5% Black, and 3.2% Hispanic.

v. Clinical Subgroups and Confounders

Subgroups included patients with obstructive CAD (9/31), normal/unobstructed coronaries (22/31), and total occlusions (2/31). Comorbidities were prevalent: hypertension (71.0%), dyslipidemia (80.6%), diabetes (35.5%), and CHF (32.3%). Indications for catheterization included STEMI (6.5%), NSTEMI (6.5%), and severe aortic stenosis (16.1%), with catheterization indications for non-CAD pathologies (e.g. aortic aneurysms, cardiac transplant) noted in 15 patients.

vi. Equipment and Protocols Used to Collect Images

Angiographic cines were sourced from the Corewell Angiographic database, captured using various models of Philips systems in March of 2025. The protocol selected diagnostic angiograms sets with major artery views, processed by AngioWaveNet and were under typical cath lab monitor and lighting conditions.

vii. Independence of Test Data from Training Data

Training data and test data were completely independent. Blinding of readers to each other's assessments and blinding from Angiowave personnel during reading prevented influence of one reader on another or of Angiowave on the readers.

10. Conclusion: After analyzing software validation, software integration validation, and physician evaluated images, it is the conclusion of AngioWave Imaging, Inc that the AngioWaveNet software is as safe and effective as the predicate device. The performance testing data demonstrate that Angiowavenet software performs comparably to the predicate device, rendering it substantially equivalent to the predicate device.