August 20, 2025

Methinks Software S.L.
Claudia Carbonell
Senior QA/RA Manager
Pier 01, Plaça de Pau Vila, Office 2D2
Barcelona, 08039
Spain

Re: K251590
Trade/Device Name: Methinks CTA Stroke
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: July 25, 2025
Received: July 25, 2025

Dear Claudia Carbonell:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251590

Device Name
Methinks CTA Stroke

Indications for Use *(Describe)*
Methinks CTA Stroke is a radiological computer aided triage and notification software, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

Methinks CTA Stroke uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation.

Identification of suspected findings is not for diagnostic use beyond notification.

Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting and sends to PACS and/or notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through an image viewer. Methinks CTA Stroke is intended to analyze terminal ICA, MCA-M1 and MCA-M2 vessels for LVOs.

Images that are previewed are for informational purposes only and not intended for diagnostic use beyond notification.

Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. Methinks CTA Stroke is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

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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"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

The content included in the 510(k) Summary of the Methinks CTA Stroke device is based on the 21 CFR 807.92 requirements.

I. SUBMITTER

Name:	Methinks Software, SL
Address:	Pier 01, Office 2D2, Plaça de Pau Vila 08039 Barcelona, Spain
Contact Person:	Claudia Carbonell
Date Prepared:	August 13, 2025

II. DEVICE

Name of Device:	Methinks CTA Stroke
Common or Usual Name:	Methinks CTA Stroke
Classification Name:	Radiological computer aided triage and notification software
Regulatory Class:	Class II
Product Code:	QAS
Regulation Number:	21 CFR §892.2080

III. PREDICATE DEVICE

The Methinks CTA Stroke device is claimed to be substantially equivalent to the following legally marketed predicate device: Viz.AI, Inc, ContaCT, DEN170073.

Name of the device	ContaCT
Classification Name:	Radiological computer aided triage and notification software
Regulatory Class:	Class II Special Control
Product Code:	QAS
Regulation Number	21 CFR §892.2080

IV. DEVICE DESCRIPTION

Methinks CTA Stroke is a software-only device which is intended to be used by trained physicians involved in the management of Acute Stroke (AS) patients at emergency settings or other departments across the stroke care pyramid model. They include trained physicians such as emergency physicians, neurologists, general radiologists, neurovascular interventionists, neuroradiologists and any trained stroke professionals.

The target patients (intended patient population) are male and female in the adult population (above 21 years old) with suspected Acute Stroke.

The Methinks CTA Stroke device analyzes Computed Tomography Angiography (CTA) images from the intended patient population to identify suspected Large Vessel Occlusions (LVO). This information is to be used in conjunction with other patient information by a professional to assist with triage/prioritization of medical images.

The input of the software is Computed Tomography Angiography (CTA) in DICOM format from patients suspected of Acute Stroke. The outputs of the software are notifications sent to the trained physicians intended to be used in conjunction with other patient information for professional judgment to assist with triage/prioritization.

V. INDICATIONS FOR USE

Methinks CTA Stroke is a radiological computer aided triage and notification software, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

Methinks CTA Stroke uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation.

Identification of suspected findings is not for diagnostic use beyond notification.

Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting and sends to PACS and/or notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through an image viewer. Methinks CTA Stroke is intended to analyze terminal ICA, MCA-M1 and MCA-M2 vessels for LVOs.

Images that are previewed are for informational purposes only and not intended for diagnostic use beyond notification.

Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. Methinks CTA Stroke is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Methinks CTA Stroke does not raise new questions of safety or effectiveness compared to the previously cleared ContaCT (DEN170073). Both devices are radiological computer-aided triage and notification software applications for determining suspicion of Large Vessel Occlusion (LVO). Both devices use CT angiogram images for the identification of suspected LVO cases.

Compared to the predicate device, the subject device identifies an additional type of occlusion MCA-M2 (the predicate identifies ICA and MCA-M1 only) which does not raise a substantial difference in the indications for use nor different questions of safety and effectiveness.

Identification of suspected findings for both devices are not for diagnostic use beyond notification.

The following table summarizes and compares Methinks CTA Stroke and the ContaCT device (predicate device). A table comparing the key features of the subject and the predicate devices is provided below:

Table 1. Substantial Equivalence Table.

Substantial Equivalence Table		
Comparison Feature	**Predicate Device: ContaCT**	**Subject Device: Methinks CTA Stroke**
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Indications for Use	ContaCT is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, 1 independent of standard of care workflow. ContaCT uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting,and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.	Methinks CTA Stroke is a radiological computer aided triage and notification software, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow. Methinks CTA Stroke uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting, and sends to PACS and/or notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through an image viewer. Methinks CTA Stroke is intended to analyze terminal ICA, MCA-M1 and MCA-M2 vessels for LVOs. Images that are previewed are for informational purposes only and not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. Methinks CTA Stroke is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.
User	Trained Clinicians	Trained Physicians
Anatomy	Head	Head
Input Data	CT Angiography images	CT Angiography images
Technology	Artificial intelligence/ Neural Network	AI/ML/Neural Network
Segmentation of ROI	The device does not highlight or direct a user's attention to a specific location in the image file.	The device does not highlight or direct a user's attention to a specific location in the image file.
Preview Images	Images that are previewed are for informational purposes only and not intended for diagnostic use beyond notification.	Images that are previewed are for informational purposes only and not intended for diagnostic use beyond notification.
Annotation/Localization	The device does not mark, highlight, or direct users' attention to a specific location in the	The device does not mark, highlight, or direct users' attention to a specific location in the

	original image.	original image.
Prioritization Notification	Yes	Yes
Clinical SoC Workflow	In parallel to	In parallel to
Technical Pipeline	Large Vessel Occlusion (LVO) Notification (one output)	Large Vessel Occlusion (LVO) Notification (one output)
Removal of Cases from SoC review	No	No

VII. PERFORMANCE STANDARDS AND DATA

Performance Data

Cybersecurity has been integrated into the design and development of the Methinks CTA Stroke device in accordance with FDA's cybersecurity guidance and Section 524B of the FD&C Act. The device underwent rigorous non-clinical testing under clinically relevant conditions. Design verification and validation per 21 CFR Part 820.30 confirmed that all design requirements and specifications were met.

Methinks employed a risk-based cybersecurity strategy that includes secure design principles, threat modeling, vulnerability assessment, third-party penetration testing and a Software Bill of Materials (SBOM). Key security controls such as authentication, authorization, secure update mechanisms, and system logging have been implemented. Cybersecurity was addressed as part of the software verification process. Controls including authentication, authorization, cryptography, code, data and execution integrity, confidentiality, monitoring, resiliency and recovery, software updates, patch management, and coordinated vulnerability disclosure are in place to ensure ongoing safety, effectiveness and resilience against cybersecurity threats throughout the device lifecycle.

Methinks conducted a retrospective, blinded, multicenter, multinational study with the Methinks CTA Stroke device with the primary endpoint to evaluate the software's performance in identifying CTA images containing Large Vessel Occlusion (LVO) findings in 336 cases for LVO (LVO Positive: 110, LVO Negative: 226). Institutions included in the validation study were different from institutions included in training, to ensure separation and better representativity of the validation results. This was ensured by checking the countries, states and ZIP codes, when necessary, of the institutions involved.

Ground truthing was established by two US board certified neuroradiologists that read the cases and a third ground truther in case the two first readers were in disagreement regarding LVO findings. The final ground truth was established based on the majority vote.

Sensitivity and specificity exceed the pre-specified performance goals for LVO. Specifically, LVO was observed at Sensitivity: 98.2% (95% CI: 93.6% - 99.8%) and Specificity: 91.6% (95% CI: 87.2% - 94.9%).

The Methinks CTA Stroke time to notification analysis includes the time to get the DICOM exam, de-identify it (if required), analyze and send a notification back to the PACS and notification clients. Methinks CTA Stroke time to notification has been documented for all cases with results shown in the following table.

Table 2. Time to notification of Methinks CTA Stroke.

Parameter	Mean	95% CI Lower	95% CI Upper
Time to notification of CTA-LVO (minutes)	3.30	3.23	3.36

Performance across subgroups

Subgroup analyses were conducted for the LVO indication, to support the generalizability of the device across intended patient population and device input.

Performance metrics by subgroups for Methinks CTA Stroke:

Table 3. Performance metrics CTA-LVO by Gender.

Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Male	Sensitivity	53	96.2%	87.0%	99.5%
	Specificity	115	92.2%	85.7%	96.4%
Female	Sensitivity	57	100.0%	93.7%	100.0%
	Specificity	111	91.0%	84.1%	95.6%

Table 4. Performance metrics CTA-LVO by Age.

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 50 years	Sensitivity	8	100.0%	63.1%	100.0%
	Specificity	40	97.5%	86.8%	99.9%
50 - 70 years	Sensitivity	41	97.6%	87.1%	99.9%
	Specificity	106	92.5%	85.7%	96.7%
> 70 years	Sensitivity	61	98.4%	91.2%	100.0%
	Specificity	80	87.5%	78.2%	93.8%

Table 5. Performance metrics CTA-LVO by vendor machine.

Vendor machine	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Siemens	Sensitivity	35	97.1%	85.1%	99.9%
	Specificity	83	92.8%	84.9%	97.3%
General Electric	Sensitivity	20	100.0%	83.2%	100.0%

	Specificity	31	83.9%	66.3%	94.5%
Philips	Sensitivity	34	97.1%	84.7%	99.9%
	Specificity	82	91.5%	83.2%	96.5%
Toshiba / Canon	Sensitivity	21	100.0%	83.9%	100.0%
	Specificity	30	96.7%	82.8%	99.9%

Table 6. Performance metrics CTA-LVO by LVO subgroup.

LVO subgroups	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
ICA	Sensitivity	35	100.0%	90.0%	100.0%
	Specificity	0	-	-	-
MCA-M1	Sensitivity	44	100.0%	92.0%	100.0%
	Specificity	0	-	-	-
ICA + MCA-M1	Sensitivity	76	100.0%	95.3%	100.0%
	Specificity	0	-	-	-
MCA-M2	Sensitivity	25	92.0%	74.0%	99.0%
	Specificity	0	-	-	-

Table 7. Performance metrics CTA-LVO by slice thickness.

Slice thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
0.3mm ≤ slice thickness ≤ 1mm	Sensitivity	91	97.8%	92.3%	99.7%
	Specificity	198	92.9%	88.4%	96.1%
1mm < slice thickness ≤ 1.3mm	Sensitivity	19	100.0%	82.4%	100.0%
	Specificity	28	82.1%	63.1%	93.9%

Table 8. Performance metrics CTA-LVO by non-LVO subgroup.

Non-LVO subgroups	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Tumors	Sensitivity	0	-	-	-

	Specificity	2	100.0%	15.8%	100.0%
Stenosis > 51%	Sensitivity	0	-	-	-
	Specificity	27	74.1%	53.7%	88.9%
Intracranial Hemorrhage (ICH)	Sensitivity	0	-	-	-
	Specificity	3	100.0%	29.2%	100.0%
Other Acute Ischemic Events	Sensitivity	0	-	-	-
	Specificity	61	78.7%	66.3%	88.1%
Chronic Lesions	Sensitivity	0	-	-	-
	Specificity	101	86.1%	77.8%	92.2%
No Findings (none of the above)	Sensitivity	0	-	-	-
	Specificity	162	96.3%	92.1%	98.6%

In summary, the performance validation data demonstrated that the proposed device provides accurate detection of acute LVO under a range of clinically relevant variables associated with the intended use of the device. The notification functionality of the device also met the acceptance criteria.

Substantial Equivalence Discussion

Both devices have identical intended use and similar technological characteristics/features and roles within a clinical workflow relative to triage and notification. Both devices are intended to automatically process and analyze CT angiogram images to provide a notification to users in case of a suspected LVO being identified.

The subject device does not introduce any new risks when compared to the predicate and both include similar mitigation strategies for reducing the risk of off label use of preview images which are shared via mobile.

VIII. CONCLUSIONS

In conclusion, Methinks CTA Stroke is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, ContaCT (DEN170073).