June 16, 2025

Methinks Software S.L.
% Claudia Carbonell
Senior QA/RA Manager
Methinks Software, S.L.
Pier 01, Plaça Pau Vila 1, Office 2D2
Barcelona, 08039, Spain

Re: K250685
Trade/Device Name: Methinks NCCT Stroke
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: May 12, 2025
Received: May 12, 2025

Dear Nima Akhlaghi:

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.

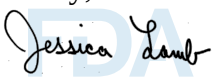
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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.
Imaging Software Team
Assistant Director
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.

Submission Number *(if known)*

K250685

Device Name

Methinks NCCT Stroke

Indications for Use *(Describe)*

Methinks NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) non-contrast head CT (NCCT) images. The device is intended to assist hospital networks and trained physicians in workflow triage by flagging and communicating suspected positive findings of (1) Intracranial Hemorrhage (ICH) and (2) Large Vessel Occlusion (LVO) of the ICA, MCA-M1 and MCA-M2.

Methinks NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with suspected (1) ICH and (2) LVO in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS and/or notifications. Notifications include preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification.

The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device. The results of Methinks NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Methinks NCCT Stroke is for adults only.

Cautions:
- All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output.
- The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for "LVO Suspected" should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup.

Limitations
- The device does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification 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.

510(k) Summary

The content included in the 510(k) Summary of the Methinks NCCT 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:	May 7, 2025

II. DEVICE

Name of Device:	Methinks NCCT Stroke
Common or Usual Name:	Methinks NCCT 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 NCCT Stroke device is claimed to be substantially equivalent to the following legally marketed predicate device: iSchemaView, Inc, Rapid NCCT Stroke, K222884.

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

IV. DEVICE DESCRIPTION

Methinks NCCT Stroke is a radiological computer-assisted triage and notification software device. The device receives Non-Contrast Computed Tomography (NCCT) images and processes them to provide triage and notification prioritization of suspected Intracranial Hemorrhage (ICH) and Large Vessel Occlusion (LVO) of the ICA, MCA-M1 and MCA-M2. The Methinks NCCT Stroke device is an AI/ML Software as a Medical Device. The outputs of the device are intended to be used by trained clinicians in the prioritization of patients with suspected ICH and/or LVO.

V. INDICATIONS FOR USE

Methinks NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) non-contrast head CT (NCCT) images. The device is intended to assist hospital networks and trained physicians in workflow triage by flagging and communicating suspected positive findings of (1) Intracranial Hemorrhage (ICH) and (2) Large Vessel Occlusion (LVO) of the ICA, MCA-M1 and MCA-M2.

Methinks NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with suspected (1) ICH and (2) LVO in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS and/or notifications. Notifications include preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification.

The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device. The results of Methinks NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Methinks NCCT Stroke is for adults only.

Cautions:

- All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output.
- The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for “LVO Suspected” should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup.

Limitations:

- The device does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Methinks NCCT Stroke does not raise new questions of safety or effectiveness compared to the previously cleared Rapid NCCT Stroke (K222884). Both devices are radiological computer-aided triage and notification software applications for determining suspicion of ICH and LVO. Both devices use NCCT images for the determination of suspected ICH and LVO.

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 or effectiveness.

The benefits include the shorter time to a suspected LVO notification by assessing non-contrast imaging immediately, then CTA follow-up per standard of care for stroke workup. Thus, the Methinks NCCT Stroke is substantially equivalent to the Rapid NCCT Stroke device.

The following table summarizes and compares Methinks NCCT Stroke and the Rapid NCCT Stroke 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: Rapid NCCT Stroke**	**Subject Device: Methinks NCCT Stroke**
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
	Rapid NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) nonenhanced head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) NCCT large vessel occlusion (LVO) of the ICA and MCA-M1. Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device. The results of Rapid NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Rapid NCCT Stroke is for Adults only. Cautions: ● All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output ● The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for “Suspected LVO” should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup. Limitations: ● Rapid NCCT Stroke does not replace the need for CTA or MRA in ischemic stroke workup, it provides workflow prioritization and notification only.	Methinks NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) non-contrast head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of (1) Intracranial Hemorrhage (ICH) and (2) Large Vessel Occlusion (LVO) of the ICA, MCA-M1 and MCA-M2. Methinks NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH and (2) LVO in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS and/or notifications. Notifications include preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device. The results of Methinks NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Methinks NCCT Stroke is for adults only. Cautions: ● All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output. ● The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for “LVO Suspected” should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup. Limitations: • The device does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification only.

	• Rapid ICH has been shown to reliably identify hemorrhages of ≥ 0.4ml. Contraindications/Exclusions • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma • Very thin or no Ventricles.	
User	Trained Clinicians	Trained Physicians
Anatomy	Head	Head
Input Data	NCCT images	NCCT images
Technology	AI/ML/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	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care.	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care.
Annotation/Localization	Device does not mark, highlight, or direct users' attention to a specific location in the original image.	Device does not mark, highlight, or direct users' attention to a specific location in the original image.
Prioritization Notification	Yes	Yes
Clinical SoC Workflow	In parallel to	In parallel to
Technical Pipeline	Two cascaded functions (ICH then LVO) using three integrated algorithms.	Single algorithm with two different outputs (ICH and LVO).
Removal of Cases from SoC review	No	No

VII. PERFORMANCE STANDARDS AND DATA

Performance Data

The Methinks NCCT Stroke device underwent rigorous non-clinical testing to confirm that it meets all specified design requirements under clinically relevant conditions. Software performance, validation and verification testing demonstrated that the Methinks NCCT Stroke device meets all design requirements and specifications. Design Verification and Validation according to 21 CFR Part 820.30 passed. Cybersecurity has been considered and addressed as part of the software verification process, in line with Section 524B of the FD&C Act as a Cyber device. Methinks implemented a risk-based cybersecurity strategy including secure design principles, vulnerability assessment, Software Bill of Materials (SBOM), and penetration testing. These activities ensure the software's safety, effectiveness, and robustness against potential cybersecurity threats.

Methinks conducted a retrospective, blinded, multicenter, multinational study with the Methinks NCCT Stroke device with the primary endpoint to evaluate the software's performance in identifying NCCT head images containing intracranial hemorrhage (ICH) and

Large Vessel Occlusion (LVO) findings in 358 (ICH Positive: 132, ICH Negative: 226) for the ICH and 335 cases for LVO (LVO Positive: 110, LVO Negative: 225).
Sensitivity and specificity exceed the pre-specified performance goals for ICH and LVO. Specifically, ICH performance was observed at Se: 94.7% (95% CI: 89.3% - 97.8%), Sp: 99.5% (95% CI: 97.5% - 99.9%) and LVO was observed at Se: 76.4% (95% CI: 67.3% - 83.9%) and Sp: 91.1% (95% CI: 86.6% - 94.5%).

In addition, a reader study was conducted to compare NCCT LVO sensitivity of the device to that of radiologists. Secondary endpoints of expert non-inferiority and non-expert superiority were used for sensitivity. Methinks NCCT Stroke passed both conditions. LVO sensitivity (Se) for expert neuroradiologists was 50.0% (40.1% - 59.9%), with a difference in Se between Methinks NCCT Stroke and experts of 23.6% (95%CI: 8.5% - 38.7%), showing superiority of the Methinks device; Se for general radiologists (non-experts) was 37.7% (95% CI: 28.5% - 47.7%), and with a difference in Se between Methinks NCCT Stroke and non-experts of 35.9% (95% CI: 16.0% - 42.9%), also showing superiority of the Methinks device. The results of the reader study are included in the following table.

Table 2. Performance of the readers vs Methinks NCCT-LVO in the reader study.

	Sensitivity (95% CI)	**Specificity (95% CI)**
Methinks NCCT-LVO	73.6% (59.7% - 84.7%)	89.1% (82.0% - 94.1%)
R1 + R2 (Experts)	50.0% (40.1% - 59.9%)	92.0% (87.8% - 95.1%)
R3 + R4 (Non-experts)	37.7% (28.5% - 47.7%)	87.4% (82.5% - 91.3%)
R1 + R2 + R3 + R4 (All)	43.9% (37.1% - 50.8%)	89.7% (86.6% - 92.3%)

The Methinks NCCT 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 NCCT Stroke time to notification has been documented for all cases with results shown in the following table.

Table 3. Time to notification of Methinks NCCT Stroke.

Parameter	**Mean**	**95% CI Lower**	**95% CI Upper**
Time to notification of NCCT-ICH (minutes)	1.43	1.36	1.50
Time to notification of NCCT-LVO (minutes)	1.42	1.36	1.48

Performance across subgroups

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

Performance metrics by subgroups for NCCT-ICH

Table 4. performance metrics NCCT-ICH by Gender.

Gender	**Measure**	**N**	**Estimate**	**Lower 95% CI**	**Upper 95% CI**
Male	Sensitivity	76	97.4%	90.8%	99.7%

	Specificity	119	99.2%	95.4%	100.0%
Female	Sensitivity	55	90.9%	80.0%	97.0%
	Specificity	107	100.0%	96.6%	100.0%
Unspecified	Sensitivity	1	100.0%	2.5%	100.0%
	Specificity	0	-	-	-

Table 5. performance metrics NCCT-ICH by Age.

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 50 years	Sensitivity	17	94.1%	71.3%	99.9%
	Specificity	43	97.7%	87.7%	99.9%
50 - 70 years	Sensitivity	53	98.1%	89.9%	100.0%
	Specificity	98	100.0%	96.3%	100.0%
> 70 years	Sensitivity	62	91.9%	82.2%	97.3%
	Specificity	85	100.0%	95.8%	100.0%

Table 6. performance metrics NCCT-ICH by Slice Thickness.

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
1mm ≤ Slice Thickness < 2.5mm	Sensitivity	37	97.3%	85.8%	99.9%
	Specificity	77	98.7%	93.0%	100.0%
2.5mm ≤ Slice Thickness < 4mm*	Sensitivity	30	83.3%	65.3%	94.4%
	Specificity	36	97.2%	85.5%	99.9%
4mm ≤ Slice Thickness ≤ 5.5mm	Sensitivity	95	93.7%	86.8%	97.6%
	Specificity	149	100.0%	97.6%	100.0%

2.5mm ≤ Slice Thickness < 4mm are additional cases. This is why if you sum all N's it will exceed the sample size of the study.*

Table 7. performance metrics NCCT-ICH by Vendor Machine.

Vendor Machine	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Siemens	Sensitivity	83	92.8%	84.9%	97.3%
	Specificity	146	100.0%	97.5%	100.0%
General Electric*	Sensitivity	48	93.8%	85.7%	97.5%
	Negatives	22	100.0%	84.6%	100.0%
Philips	Sensitivity	47	97.9%	88.7%	99.9%
	Specificity	80	98.8%	93.2%	100.0%
Toshiba / Canon*	Sensitivity	12	100.0%	73.5%	100.0%
	Negatives	7	85.7%	42.1%	99.6%

General Electric and Toshiba/Canon are additional cases. This is why if you sum all N's it will exceed the sample size of the study.*

Table 8. performance metrics NCCT-ICH by hemorrhage volume.

Hemorrhage volume	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Smaller than 1 ml	Sensitivity	10	80.0%	44.4%	97.5%
	Specificity	0	-	-	-
Between 1 ml and 5 ml	Sensitivity	50	92.0%	80.8%	97.8%
	Specificity	0	-	-	-
Bigger than 5 ml	Sensitivity	95	96.8%	91.0%	99.3%
	Specificity	0	-	-	-

Table 9. performance metrics NCCT-ICH by hemorrhage sub-type.

Hemorrhage sub type	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Epidural hemorrhage*	Sensitivity	3	100.0%	29.2%	100.0%
	Specificity	0	-	-	-
Subdural hemorrhage*	Sensitivity	21	85.7%	63.7%	97.0%
	Specificity	0	-	-	-
Subarachnoid hemorrhage	Sensitivity	13	92.3%	64.0%	99.8%
	Specificity	0	-	-	-
Intraparenchymal hemorrhage	Sensitivity	112	97.3%	92.4%	99.4%
	Specificity	0	-	-	-
Intraventricular hemorrhage	Sensitivity	27	100.0%	87.2%	100.0%
	Specificity	0	-	-	-

Epidural hemorrhage and subdural hemorrhage are additional cases. This is why if you sum all N's it will exceed the sample size of the study.*

Performance metrics by subgroups for NCCT-LVO

Table 10. performance metrics NCCT-LVO by Gender.

Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Female	Sensitivity	56	76.8%	63.6%	87.0%
	Specificity	109	93.6%	87.2%	97.4%
Male	Sensitivity	54	75.9%	62.4%	86.5%
	Specificity	116	88.8%	81.6%	93.9%

Table 11. performance metrics NCCT-LVO by Age.

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 50	Sensitivity	7	85.7%	42.1%	99.6%
	Specificity	38	100.0%	90.7%	100.0%
50 - 70	Sensitivity	43	74.4%	58.8%	86.5%
	Specificity	103	91.3%	84.1%	95.9%
> 70	Sensitivity	60	76.7%	64.0%	86.6%
	Specificity	84	86.9%	77.8%	93.3%

Table 12. performance metrics NCCT-LVO by Slice Thickness.

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
1mm ≤ Slice Thickness < 2.5mm	Sensitivity	25	72.0%	50.6%	87.9%
	Specificity	78	91.0%	82.4%	96.3%
2.5mm ≤ Slice Thickness < 4mm	Sensitivity	35	77.1%	59.9%	89.6%
	Specificity	45	84.4%	70.5%	93.5%
4mm ≤ Slice Thickness ≤ 5.5mm	Sensitivity	50	78.0%	64.0%	88.5%
	Specificity	102	94.1%	87.6%	97.8%

Table 13. performance metrics NCCT-LVO by Vendor Machine.

Vendor Machine	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Siemens	Sensitivity	36	75.0%	57.8%	87.9%
	Specificity	86	96.5%	90.1%	99.3%
General Electric	Sensitivity	19	73.7%	48.8%	90.9%
	Specificity	28	82.1%	63.1%	93.9%
Philips	Sensitivity	34	76.5%	58.8%	89.3%
	Specificity	82	86.6%	77.3%	93.1%
Toshiba / Canon	Sensitivity	21	81.0%	58.1%	94.6%
	Specificity	29	96.6%	82.2%	99.9%

Table 14. performance metrics NCCT-LVO by LVO subgroups.

LVO Subgroups	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
ICA	Sensitivity	36	77.8%	60.8%	89.9%
	Specificity	0	-	-	-
MCA-M1	Sensitivity	44	88.6%	75.4%	96.2%
	Specificity	0	-	-	-

ICA + MCA-M1 (as predicate)	Sensitivity	77	83.1%	72.9%	90.7%
	Specificity	0	-	-	-
MCA-M2	Sensitivity	25	68.0%	46.5%	85.1%
	Specificity	0	-	-	-
LVO without ischemia	Sensitivity	33	42.4%	25.5%	60.8%
	Specificity	0	-	-	-

Out of the 33 LVO without ischemia, 18 were also tagged by radiologists only reading the NCCT image. In this subgroup where we can compare our algorithm with them the results were:

Table 15. Performance of the Methinks NCCT-LVO and Radiologists in the LVO without ischemia subgroup.

Output	**Sensitivity (95% CI)**
Methinks NCCT-LVO	38.8% (17.3% - 64.3%)
Radiologist 1	33.3% (13.3% - 59.0%)
Radiologist 2	22.2% (6.4% - 47.6%)
Radiologist 3	16.6% (3.6% - 41.4%)
Radiologist 4	11.1% (1.4% - 34.7%)

Table 16. performance metrics NCCT-LVO by non-LVO subgroups.

Non-LVO Subgroups	**Measure**	**N**	**Estimate**	**Lower 95% CI**	**Upper 95% CI**
Tumors	Sensitivity	0	-	-	-
	Specificity	2	50.0%	1.3%	98.7%
Stenosis > 51%	Sensitivity	0	-	-	-
	Specificity	28	85.7%	67.3%	96.0%
Intracranial Hemorrhage (ICH)	Sensitivity	0	-	-	-
	Specificity	3	100.0%	29.2%	100.0%
Other Acute Ischemic Events	Sensitivity	0	-	-	-
	Specificity	62	79.0%	66.8%	88.3%
Chronic Lesions	Sensitivity	0	-	-	-
	Specificity	104	89.4%	81.9%	94.6%
No Findings (none of the above)	Sensitivity	0	-	-	-
	Specificity	160	95.6%	91.2%	98.2%

In summary, the performance validation data demonstrated that the proposed device provides accurate detection of acute ICH and 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.

Safety and Effectiveness
Methinks NCCT Stroke has been designed, verified and validated in compliance with 21 CFR Part 820.30 requirements. The device has been designed to meet the requirements associated with EN ISO 14971:2019 (risk management) and the software development process conforms to ISO 62304:2015. The Methinks NCCT Stroke performance has been validated through retrospective case data based on expert reader truthing of the data and reader testing.

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 non-contrast CT scans to provide a notification to users in case of a suspected LVO or ICH 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 NCCT Stroke is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Rapid NCCT Stroke (K222884).