



November 7, 2024

Neurocareai Inc.
Junaid Siddiq Kalia
Chief Executive Officer
8992 Preston Rd Ste 110-255
Frisco, Texas 75034

Re: K241719

Trade/Device Name: NeuroICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: October 8, 2024
Received: October 8, 2024

Dear Junaid Siddiq Kalia:

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

Indications for Use

Submission Number (if known)

K241719

Device Name

NeuroICH

Indications for Use (Describe)

NeuroICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of suspected ICH patients to a specialist, independent of standard of care workflow.

The device uses an artificial intelligence algorithm to analyze non-contrast CT images of the head acquired in the acute setting for findings suggestive of intracranial hemorrhage (ICH) in parallel to the ongoing standard of care image interpretation and notify an appropriate clinician of these findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter or remove the original medical image and is not intended to be used as a diagnostic device. Images can be previewed through a mobile application.

Notified clinicians are responsible for viewing high quality images on a diagnostic viewer per the standard of care and engaging in appropriate patient evaluation in conjunction with other patient information before making care-related decisions. NeuroICH 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.

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K241719

**510(k) Summary of NeuroICH
by
NEUROCAREAI INC**

Applicant Name: NEUROCAREAI INC.
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Contact Person: Junaid Kalia
Chief Executive Officer
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Date Prepared: June 12, 2024

Device Name and Classification

Name of Device: NeuroICH

Classification Name: Radiological Computer Aided Triage and Notification Software

Common Name: Intracranial Hemorrhage Detection and Notification Software

Classification Panel: Radiology

Regulation Number: 21 C.F.R. § 892.2080

Regulatory Class: Class II

Product Code: QAS

Predicate Device:

Manufacturer	Device Name	Application Number
Viz.ai, Inc.	Viz ICH	K210209

Device Description:

NeuroICH is a software-only parallel workflow tool designed for use by hospital networks and trained clinicians to identify and communicate prioritized images of specific patients to an appropriate specialist such as neurovascular or neurosurgical specialist independent of the standard of care workflow. NeuroICH mainly consists of an image analysis module hosted on cloud, and a mobile application for preview of notification and non-diagnostic images. The standalone software device automatically receives and analyzes non-contrast head CT (NCCT) studies of patients undergoing stroke protocol, for image features that indicate the presence of an intracranial hemorrhage (ICH) using deep learning artificial intelligence algorithm, and upon detection of a suspected ICH case, sends a notification along with non-diagnostic image on mobile application to alert a specialist clinician.

Intended Use:

The intended use of NeuroICH software is to detect and notify neurovascular specialists or trained clinicians regarding the presence of intracranial hemorrhage in non-contrast head CT scan images. Intracranial hemorrhage is identified if any one of the subtypes – extradural, subdural, subarachnoid, intraparenchymal and intraventricular hemorrhages is detected. The device uses an artificial intelligence algorithm to analyze images in parallel to the ongoing standard of care image interpretation and present users with notifications and preview images of suspected ICH patients on the mobile application, that are meant for informational purposes only and not intended for diagnostic use.

Indications for Use:

NeuroICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of suspected ICH patients to a specialist, independent of standard of care workflow.

The device uses an artificial intelligence algorithm to analyze non-contrast CT images of the head acquired in the acute setting for findings suggestive of intracranial hemorrhage (ICH) in parallel to the ongoing standard of care image interpretation and notify an appropriate clinician of these findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter or remove the original medical image and is not intended to be used as a diagnostic device. Images can be previewed through a mobile application.

Notified clinicians are responsible for viewing high quality images on a diagnostic viewer per the standard of care and engaging in appropriate patient evaluation in conjunction with other patient information before making care-related decisions. NeuroICH 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.

Comparison of Technological Characteristics:

The subject device and predicate device have equivalent indications for use as both of them analyze non-contrast head CT scans of the patients for the features suggestive of the same abnormality i.e., intracranial hemorrhage and upon detection send the notification to designated neurovascular or neurosurgical specialist.

The technological characteristics of subject and predicate devices are similar as both of them use the similar process of automatic data identification and transfer to send images from the local hospital network to a remote location for image storage, processing and analysis.

Both the subject and predicate device uses a deep learning artificial intelligence algorithm to analyze non-contrast CT scan images of the head and classify cases with suspected ICH in parallel to the ongoing standard of care image interpretation. Like the predicate device, the NeuroICH algorithm does not externalize any internal segmentation, analysis, or intermediate outputs used in determining if an ICH is present in the NCCT, nor does either algorithm mark, highlight or draw attention to the specific regions of the analyzed NCCT image.

Both NeuroICH and Viz ICH software supports a mobile application interface that allows a user to receive push notifications, preview related non-diagnostic images, and view patient details associated with a series. The NeuroICH mobile application is subject to the same non-diagnostic viewing limitations as the predicate and has the same non-diagnostic warning on the image viewing screen as the predicate. Furthermore, the mobile application for both the devices can perform similar image viewing functions (window level change, image rotation, zoom, scroll through a cine, slice change).

Similar to the predicate device, the NeuroICH software does not affect the normal standard of care workflow of the hospital and moreover does not remove cases from a reading queue of the hospital PACs system. In conclusion, the NeuroICH device is substantially equivalent to the predicate device, Viz ICH in terms of both indications for use and technological characteristics.

A table comparing the key features of the subject and predicate device is provided below:

Parameter	Subject Device NeuroICH	Predicate Device Viz ICH
Indications of use	<p>NeuroICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of suspected ICH patients to a specialist, independent of standard of care workflow.</p> <p>The device uses an artificial intelligence algorithm to analyze non-contrast CT images of the head acquired in the acute setting for findings suggestive of intracranial hemorrhage (ICH) in parallel to the ongoing standard of care image interpretation and notify an appropriate clinician of these findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter or remove the original medical image and is not intended to be used as a diagnostic device. Images can be</p>	<p>Viz ICH 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, independent of standard of care workflow.</p> <p>Viz ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care for image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the brain acquired in the acute setting, and sends notifications to a neurovascular or neurosurgical specialist that a suspected intracranial hemorrhage has been identified and recommends review</p>

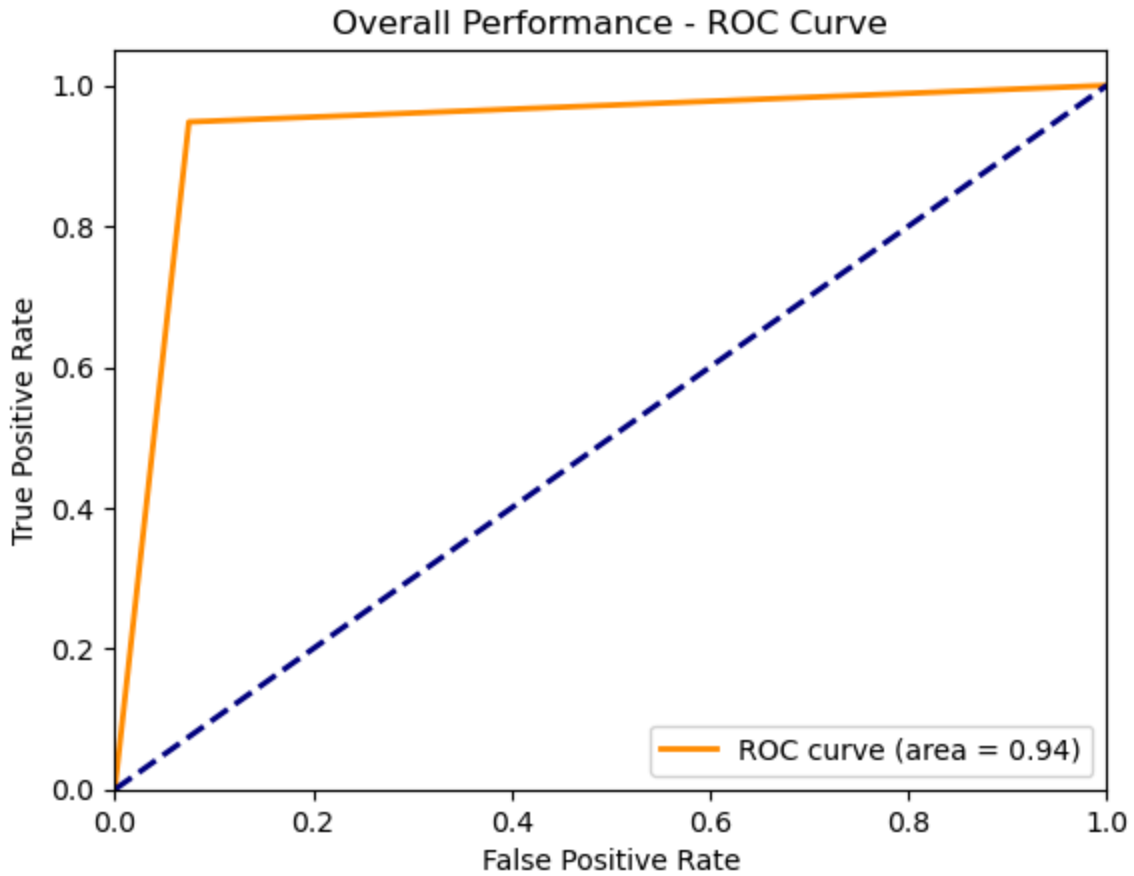
	<p>previewed through a mobile application.</p> <p>Notified clinicians are responsible for viewing high quality images on a diagnostic viewer per the standard of care and engaging in appropriate patient evaluation in conjunction with other patient information before making care-related decisions. NeuroICH 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.</p>	<p>of those images. Images can be previewed through a mobile application.</p> <p>Images that are previewed through the mobile application may be 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. Viz ICH 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.</p>
Device components	<ol style="list-style-type: none"> 1. Image forwarding module configured on site machine at hospital end for transferring DICOM studies. 2. Image analysis software algorithm hosted on AWS cloud managed by NEUROCAREAI. 3. Mobile application software module for review of notification and non-diagnostic images. 4. Admin panel as web application for registration and management of systems, sites and clinicians accounts. 	<ol style="list-style-type: none"> 1. Image analysis software algorithm hosted on Viz.ai's servers. 2. Mobile application software module for review of notification and non-diagnostic images.
Anatomical region of interest	Head	Head
Diagnostic application	Notification only	Notification only
Intended user	Neurovascular or Neurosurgical Specialist	Neurovascular or Neurosurgical Specialist
Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities.	Acquires medical image data from DICOM compliant imaging devices and modalities.
Data acquisition protocol	Non contrast CT scan of the head	Non contrast CT scan of the head

DICOM compatible	Yes	Yes
View DICOM data	DICOM Information about the patient, study, and current image	DICOM Information about the patient, study and current image
Segmentation of the region of interest	No; the device does not mark, highlight, or direct users' attention to a specific location in the original image.	No; the device does not mark, highlight, or direct users' attention to a specific location in the original image.
AI used	Yes	Yes
Notification	Yes	Yes
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, which remains the default option for all cases.	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, which remains the default option for all cases.
Alteration of original image	No	No
Removal of cases from worklist queue	No	No
Abnormalities triaged	ICH	ICH
Preview image information	Preview images returned to the Mobile application for view.	Preview images returned to the Mobile application for view.

Performance Data:

A retrospective, blinded study was conducted to evaluate the software's performance in identifying non-contrast (NCCT) head CT scans containing intracranial hemorrhage (ICH). Primarily 376 studies were used with recognizable representation of positive and negative ICH cases (35.90 % ICH positive studies and 64.09 % normal studies) to calculate Sensitivity (Se), Specificity (Sp), Accuracy, Area Under the Curve (AUC) and Time-to-Notification (TTN) regarding suspected ICH case.

Sensitivity, specificity, AUC and accuracy were calculated as primary endpoints with 95% clopper-pearson confidence interval, comparing the NeuroICH's output to the ground truth as established by three US board certified Neurologists. Sensitivity and specificity on the primary dataset were observed to be 94.81% (89.68% - 97.43%) and 92.53% (88.50% - 95.21%), respectively. Because the lower bound of each confidence interval exceeded 80%, the study met the pre-specified performance goals of 80% for sensitivity and specificity and was comparative to the values achieved by the predicate device Viz ICH. In addition, the accuracy and area under the receiver operating characteristic curve (AUC) were 93.35% (90.37% - 95.45%) and 0.9367 respectively, demonstrating the clinical utility and potential benefits of the classifier based on the imaging study results.



The performance metrics were calculated for individual data distributions as well to showcase the evaluation on important data cohorts. The stratification of device performance is demonstrated in tables below:

Device Performance by Age		
Age Range (Years)	Sensitivity [95% CI]	Specificity [95% CI]
22 to 50	94.87% (83.08% - 98.43%)	89.86% (80.48% - 94.93%)
50 to 70	95.83% (86.02% - 98.72%)	92.05% (84.46% - 96.04%)
70 +	93.75% (83.13% - 97.73%)	95.24% (88.39% - 98.06%)

Device Performance by Gender		
Gender	Sensitivity [95% CI]	Specificity [95% CI]
Male	93.07% (86.37% - 96.55%)	90.91% (84.74% - 94.30%)

Female	100% (90% - 99.93%)	96.92% (89.48% - 99.05%)
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Device Performance by Slice Thickness		
Slice Thickness	Sensitivity [95% CI]	Specificity [95% CI]
2 mm ≤ Slice Thickness < 3 mm	96.15% (81.03% - 99.09%)	98% (89.55% - 99.52%)
3 mm ≤ Slice Thickness ≤ 5 mm	94.50% (88.51% - 97.40%)	91.10% (86.20% - 94.35%)

Device Performance by ICH Sub-Type	
ICH Sub-Type	Sensitivity [95% CI]
Subdural Hemorrhage	91.89% (83.40% - 96.16%)
Intraparenchymal Hemorrhage	98.25% (90.76% - 99.58%)
Subarachnoid Hemorrhage	100% (93.40% - 99.95%)
Intraventricular Hemorrhage	96.43% (82.24% - 99.15%)
Epidural Hemorrhage	100% (71.51% - 99.77%)

Device Performance by Scanner Manufacturer		
Scanner Manufacturer	Sensitivity [95% CI]	Specificity [95% CI]
GE Medical Systems	94.44% (81.81% - 98.30%)	95.60% (91.57% - 97.73%)
Siemens	94.25% (87.24% - 97.46%)	84.62% (72.41% - 91.93%)
Philips	100% (63.06% - 99.68%)	100% (29.24% - 99.16%)
Siemens Healthineers	N/A	75% (28.36% - 94.73%)
TOSHIBA	100% (54.07% - 99.58%)	0% (1.26% - 84.19%)

Device Performance by CT Scanner Make/Model			
Scanner Manufacturer	Scanner Model	Sensitivity [95% CI]	Specificity [95% CI]
GE Medical Systems	Optima CT660	66.67% (19.41% - 93.24%)	95.10% (90.24% - 97.57%)
	Revolution CT	100% (87.66% - 99.91%)	50% (9.43% - 90.57%)
	Revolution EVO	83.33% (42.13% - 96.33%)	100% (88.43% - 99.92%)
	Discovery RT	N/A	100% (29.24% - 99.16%)
	Discovery 690	N/A	100% (54.07% - 99.58%)
	LightSpeed Pro 16	N/A	100% (15.81% - 98.74%)
Siemens	SOMATOM Drive	100% (29.24% - 99.16%)	100% (73.54% - 99.79%)
	SOMATOM Perspective	90% (58.72% - 97.72%)	88.89% (55.50% - 97.48%)
	SOMATOM Definition AS	100% (92.13% - 99.94%)	77.78% (44.39% - 93.33%)
	SOMATOM Definition AS+	100% (82.35% - 99.87%)	75% (46.19% - 90.91%)
	SOMATOM go.Up	50% (9.43% - 90.57%)	100% (39.76% - 99.37%)
	Perspective	70% (39.03% - 89.07%)	80% (35.88% - 95.67%)
	SOMATOM Definition Edge	100% (15.81% - 98.74%)	N/A
	SOMATOM go.Top	N/A	33% (6.76% - 80.59%)
	Biograph Horizon	N/A	100% (15.81% - 98.74%)

Philips	Brilliance 16	100% (59.04% - 99.64%)	100% (29.24% - 99.16%)
	Incisive CT	100% (15.81% - 98.74%)	N/A
Siemens Healthineers	SOMATOM go.UP	N/A	50% (9.43% - 90.57%)
	SOMATOM go.Top	N/A	100% (29.24% - 99.16%)
TOSHIBA	Aquilion	100% (29.24% - 99.16%)	N/A
	Aquilion ONE	100% (29.24% - 99.16%)	NA
	Aquilion PRIME	100% (15.81% - 98.74%)	0% (1.26% - 84.19%)

Device Performance by ICH Volume		
Minimal Volume Threshold (mL)	Sensitivity Above Threshold [95% CI]	Sensitivity Below/Equal Threshold [95% CI]
1	100% (91.96% - 99.94%)	92.86% (68.05% - 98.34%)
5	100% (87.23% - 99.91%)	96.77% (83.78% - 99.23%)
10	100% (83.89% - 99.88%)	97.30% (86.19% - 99.36%)

Device Performance by Scanner Reconstruction Method			
Scanner Manufacturer	Reconstruction Method	Sensitivity [95% CI]	Specificity [95% CI]
GE Medical Systems	STANDARD	93.94% (80.32% - 98.14%)	95.60% (91.57% - 97.73%)
	SOFT	100% (39.76% - 99.37%)	N/A
Siemens	J37f, 3	100% (29.24% - 99.16%)	100% (73.54% - 99.79%)
	J30s, 2	84% (65.13% - 93.45%)	88.24% (65.29%- 96.42%)

	H31f	100% (88.06% - 99.91%)	66.67% (19.41%- 93.24%)
	J37f, 2	100% (76.84% - 99.82%)	50.00% (%18.41% - 81.59%)
	Hr40f, 3	50% (9.43% - 90.57%)	80.00% (35.88%- 95.67%)
	Hf38s	100% (15.81% - 98.74%)	N/A
	H30s	100% (63.06% - 99.68%)	100% (63.06% - 99.68%)
	J37s, 2	100% (47.82% - 99.49%)	0% (0.84% - 70.76%)
	Hc40f, 2	100% (29.24% - 99.16%)	N/A
	J30s, 1	100% (29.24% - 99.16%)	N/A
	Hr38s	N/A	100% (15.81% - 98.74%)
	H30f	100% (15.81% - 98.74%)	N/A
Philips	U, B	100% (63.06% - 99.68%)	100% (29.24% - 99.16%)
Siemens Healthineers	Hr40f, 3	N/A	75% (28.36% - 94.73%)
TOSHIBA	FC68	100% (29.24% - 99.16%)	0% (1.26% - 84.19%)
	FC26	100% (29.24% - 99.16%)	N/A
	FC23	100% (15.81% - 98.74%)	N/A

As a secondary endpoint, the clinical benefit of using NeuroICH to prioritize these NCCT scans was quantified by comparing the time to open exam by a radiologist in the Standard of Care (TTO) referenced from Viz ICH versus the time that NeuroICH notification was received (TTN) for all the 128 eligible head CT scans included in the standalone performance study. The NeuroICH time-to-notification (TTN) includes the time to get the DICOM exam, analyze and send a notification to the mobile application component. The standard of care time-to-open-exam (TTO) consisted of the time from the initial scan of the patient to when the

radiologist first opened the exam for review. It was referenced from the literature and the predicate device Viz ICH.

The average time to alert a specialist by NeuroICH was 0.37 ± 0.20 minutes, which is lower than the average time to open an exam seen in the Standard of Care 18.3 ± 14.2 minutes and comparable to the time reported by the predicate device Viz ICH 0.49 ± 0.08 minutes. This result generally demonstrates that specialists have the opportunity to become involved in the clinical workflow early with notifications from the NeuroICH software.

Device Performance by Time		
Parameter	NeuroICH Time with Standard Deviation	Viz ICH Time with Standard Deviation
Time to Notification (TTN)	0.37 ± 0.20 minutes	0.49 ± 0.08 minutes

Conclusion:

NeuroICH is as safe and effective as the legally marketed predicate device, Viz ICH (K210209). It shares the same indications for use and has similar technological characteristics and principles of operation as Viz ICH. The minor differences in technological characteristics do not raise any new safety concerns. Additionally, performance data demonstrate substantial equivalence to the predicate device and detects ICH in critical patients with comparable accuracy. Therefore, NeuroICH is claimed to be substantially equivalent to Viz ICH.