November 25, 2025

mlHealth 360
% Sujata Ghatpande
Regulatory Consultant
Product Success Inc.
#7, 1 Aspenwood Drive
Port Moody, BC V3H4X8
Canada

Re: K250694
Trade/Device Name: Scaida BrainCT-ICH (v1.0)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: October 28, 2025
Received: October 28, 2025

Dear Sujata Ghatpande:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250694

Please provide the device trade name(s).

Scaida BrainCT-ICH

Please provide your Indications for Use below.

Scaida BrainCT-ICH is a radiological computer aided notification software indicated for use in the analysis of non-contrast head CT images of adult patients (ages 22 and above).

The device is intended to assist trained radiologists in workflow triage by flagging and communicating suspected positive findings of pathologies in head CT images, for Intracranial Hemorrhages (ICH). The suspected ICH could be part of any of these five subtypes: Intraparenchymal hemorrhage (IPH), Intraventricular hemorrhage (IVH), Subarachnoid hemorrhage (SAH), Subdural hemorrhage (SDH), and Epidural Hemorrhage (EDH). The Scaida BrainCT-ICH device does not provide this ICH subclassification to the user; it uses an artificial intelligence algorithm to analyze images, and it identifies cases with suspected ICH only.

The device does not alter the original medical image, does not remove cases from the queue, and is not intended to be used as a diagnostic device or for use in patients under 22 years of age. If the clinician does not view the case, or if a case is not flagged, cases remain to be processed per the standard of care.
The results of Scaida BrainCT-ICH 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 radiologists are responsible for viewing full images per the standard of care.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Contact Details: 21 CFR 807.92 (a) (1)

Contact Details:

Applicant Name	mlHealth 360 Inc.
Applicant Address	Unit 204, 9900 King George Blvd Surrey BC V3T0K9 Canada
Applicant Contact Telephone	+1(604) 369-087
Applicant Contact	Mr. Kumar Surender Sinwar
Applicant Contact Email	surender@mlhealth360.com
Correspondent Name	Product Success Inc.
Correspondent Address	#7, 1 Aspenwood Drive Port Moody BC V3H4X8 Canada
Correspondent Contact Telephone	5144418227
Correspondent Contact	Sujata Ghatpande
Correspondent Contact Email	sujata@ps.inc

Device Name: 21 CFR 807.92 (a) (2)

Device Name	Scaida BrainCT-ICH
Common Name	Radiological computer aided triage and notification software
Classification Name	Radiological Computer-Assisted Triage And Notification Software
Regulation Number	892.2080
Product Code(s)	QAS

Legally Marketed Predicate Devices: 21 CFR 807.92 (a) (3)

Predicate #	K211179
Predicate Trade Name (Primary Predicate is listed first)	InferRead CT Stroke.AI
Product Code	QAS

Device description summary 21 CFR 807.92 (a) (4)

Scaida BrainCT-ICH is a radiological computer-assisted triage and notification software device that alerts of suspected intracranial hemorrhage (ICH) condition by analyzing non-contrast CT images.

The software needs to be integrated with a third-party worklist application to receive analysis requests and the corresponding DICOM images and return the ICH findings (whether suspected ICH is found) to the worklist to alert the radiologists. Scaida BrainCT-ICH solely provides a suspected ICH finding: displaying the detection is at the user's own discretion.

The device will be integrated as a part of a hospital's or a clinic's imaging workflow.

The device has no user interface and is a software-only device that has no contact with the patient.

Intended use/Indications for Use (a) (5)

Scaida BrainCT-ICH is a radiological computer aided notification software indicated for use in the analysis of non-contrast head CT images of adult patients (ages 22 and above).

The device is intended to assist trained radiologists in workflow triage by flagging and communicating suspected positive findings of pathologies in head CT images, for Intracranial Hemorrhages (ICH). The suspected ICH could be part of any of these five subtypes: Intraparenchymal hemorrhage (IPH), Intraventricular hemorrhage (IVH), Subarachnoid hemorrhage (SAH), Subdural hemorrhage (SDH), and Epidural Hemorrhage (EDH). The Scaida BrainCT-ICH device does not provide this ICH subclassification to the user; it uses an artificial intelligence algorithm to analyze images, and it identifies cases with suspected ICH only.

The device does not alter the original medical image, does not remove cases from the queue, and is not intended to be used as a diagnostic device or for use in patients under 22 years of age. If the clinician does not view the case, or if a case is not flagged, cases remain to be processed per the standard of care.

The results of Scaida BrainCT-ICH 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 radiologists are responsible for viewing full images per the standard of care.

Indications for Use Comparison 21 CFR 807.92 (a) (5)

The indications for use of the subject device are the same as that of the predicate device (K211179)

Technological Comparison 21 CFR 807.92 (a) (6)

The subject device is substantially equivalent to the predicate device given the similar intended use, similar indications for use, and the overall performance from the subject device does not have significant differences as the predicate device. Both devices leverage artificial intelligence algorithms to identify ICH findings from non-contrast brain CT scans, and notify the radiologists to assist them in triage of medical images. Both devices are also intended to be used in conjunction with the clinician's professional judgement.

Results presented with this submission demonstrate that the Scaida BrainCT-ICH device is as safe and effective as the legally marketed predicate device InferRead CT Stroke.AI (K211179), as per the comparison table below.

Item	**Scaida BrainCT-ICH (Subject device)**	**InferRead CT Stroke.AI K211179 (Predicate device)**	**Comparison**
Intended use/indications for use	Radiological computer aided notification software indicated for use in the analysis of non-contrast head CT images of adult patients. The device is intended to assist trained radiologists in workflow triage by flagging and communicating suspected positive findings of Intracranial Hemorrhage (ICH).	Radiological computer aided triage and notification software for use in the analysis of Non-Enhanced Head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging suspected positive findings of Intracranial Hemorrhage (ICH).	Same
User population	Radiologist	Radiologist	Same
Patient population	Adult	Adult	Same
Anatomical region of interest	Head	Head	Same
Data acquisition protocol	NCCT	NCCT	Same
Segmentation of region of interest	No	No	Same
Algorithm	AI algorithm with database of images	AI algorithm with database of images	Same
Notification/ prioritization	Yes	Yes, case-level indicator	Same
Preview images	No	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	Preview of images is not available
Alteration of original image	No	No	Same
Removal of cases from worklist queue	No	No	Same

Clinical standard of care workflow	In parallel to	In parallel to	Same
Design: DICOM compliance	Yes	Yes	Same
Design: Computer Platform	Standard off-the-shelf server or virtual server	Standard off-the-shelf server or virtual server	Same
Design: Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Energy used and/or delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	Same
Materials	N/A – Software only device	N/A – Software only device	Same
Biocompatibility	N/A – Software only device	N/A – Software only device	Same
Sterility	N/A – Software only device	N/A – Software only device	Same
Electrical Safety	N/A – Software only device	N/A – Software only device	Same
Mechanical Safety	N/A – Software only device	N/A – Software only device	Same
Chemical Safety	N/A – Software only device	N/A – Software only device	Same
Thermal Safety	N/A – Software only device	N/A – Software only device	Same
Radiation Safety	N/A – Software only device	N/A – Software only device	Same

A history of safe use has been established for the predicate device with no history of design-related recalls or adverse events found in FDA databases (no Medical Device Recalls, no MAUDE entries related to safety and performance).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Tests

The following non-clinical tests were conducted:

1. Software Verification and Validation:
Purpose: Software testing was conducted on the key software components of Scaida BrainCT–ICH to ensure the reliability, accuracy, and security of image processing and display functionalities.
Tests Included: Verification of software requirements and risk controls

2. Retrospective study to evaluate software performance: We conducted a retrospective study with the Scaida BrainCT-ICH device to evaluate the software performance in identifying intracranial hemorrhage (ICH) findings from non-contrast head computed tomography (CT) scans. This study leveraged a deep learning algorithm to differentiate images containing ICH or not, using ground truth images annotated by trained neuro-radiologists, and therein provide notification from the findings.

Clinical Tests

Clinical tests were not conducted as our comprehensive analysis and documentation, including nonclinical tests and performance evaluations, have provided substantial evidence demonstrating the equivalence of Scaida BrainCT-ICH to the predicate device.

Conclusions

Below are the conclusions that were drawn based on nonclinical tests conducted comparing Scaida BrainCT-ICH and the predicate device:

1. Software Verification and Validation:

Conclusion: Rigorous software verification and validation processes were conducted, ensuring that the subject device functions accurately and reliably when compared to the predicate device. 100% of the tests passed verification. The results demonstrated that the software meets specified requirements, providing a safe and effective platform for its intended use.

2. Performance Testing:

Conclusion: The intended use, functionality and performance of the subject device Scaida BrainCT-ICH and the predicate device are equivalent. The result of the non-clinical performance testing is evidence that the subject device performs in an equivalent manner to the predicate device.

Performance Data

mlHealth 360 Inc. conducted a retrospective study with the Scaida BrainCT-ICH device to evaluate the software performance in identifying intracerebral hemorrhage (ICH) findings from non-contrast head computed tomography (CT) scans. This study leveraged a deep learning algorithm to differentiate images containing ICH or not, using ground truth images annotated by three ABR-certified trained neuro-radiologists, and therein provide notification from the findings. In the event of a tie for ground truth annotations, the most experienced neuroradiologist was the tie breaker.

A total of 294 cases were collected from three institutions in the United States (two of which independent of the development set), including a balanced proportion of 63.9% ICH cases and 36.1% non-ICH cases. Across institutions, the data was acquired on scanners from several manufacturers, including 53.4% GE Medical, 9.9% Siemens, and 36.7% Toshiba. The data also comprised of a diverse population of 50.7% females and 49.3% males, across different age groups (15.0% aged 22-40 years old, and 85.0% aged above 40 years old). The data was collected among various ICH subgroups such as 23.4% Intraparenchymal hemorrhage (IPH), 23.4% Subdural hemorrhage (SDH), 22.9% Intraventricular hemorrhage (IVH), 22.9% Subarachnoid hemorrhage (SAH), and 7.4% Extradural/Epidural hemorrhage (EDH).

The performance of Scaida BrainCT-ICH reached a sensitivity of 0.867 (95% CI: 0.811-0.908) and a specificity of 0.887 (95% CI: 0.812-0.934). This demonstrates that this study met the pre-defined criteria on the validation dataset, having lower bounds of the CI from both sensitivity and sensitivity exceeding 80%. The area under the receiver operating characteristics (ROC) curve (AUC) was 0.926. This further demonstrates the clinically meaningful results from using the Scaida BrainCT-ICH to alert of suspected ICH from non-contrast head CT images.

Conclusions

The subject device is substantially equivalent to the predicate device given the similar intended use, similar indications for use, and the overall performance from the subject device does not have significant differences as the predicate device. Both devices leverage artificial intelligence algorithms to identify ICH findings from non-contrast brain CT scans, and notify the radiologists to assist them in triage of medical images. Both devices are also intended to be used in conjunction with the clinician’s professional judgement.

Results presented here demonstrate that the Scaida BrainCT-ICH device is as safe and effective as the legally marketed predicate device InferRead CT Stroke.AI (K211179).