April 3, 2023

Annalise-AI Pty Ltd.
% Haylee Bosshard
Regulatory Affairs Manager
Level P, 24 Campbell Street
Sydney, New South Wales 2000
AUSTRALIA

Re: K223240
Trade/Device Name: Annalise Enterprise CTB Triage Trauma
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: March 1, 2023
Received: March 1, 2023

Dear Haylee Bosshard:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Lu Jiang 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

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)*
K223240

Device Name
Annalise Enterprise CTB Triage Trauma

Indications for Use *(Describe)*
Intended context:
Annalise Enterprise is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings:
• acute subdural/epidural hematoma*
• acute subarachnoid hemorrhage*
• intra-axial hemorrhage*
• intraventricular hemorrhage*
*These findings are intended to be used together as one device.

The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage.

The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings.
Its results are not intended:
• to be used on a standalone basis for clinical decision making
• to rule out specific findings, or otherwise preclude clinical assessment of CTB studies

Intended modality:
Annalise Enterprise identifies suspected findings in non-contrast brain CT studies.

Intended user:
The device is intended to be used by trained clinicians who, as part of their scope of practice, are qualified to interpret brain CT studies.

Intended patient population:
The intended population is patients who are 22 years or older.

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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K223240

510(k) Summary

I. SUBMITTER

Company Name	Annalise-AI Pty Ltd
Address	Level P, 24 Campbell Street Sydney, NSW 2000 Australia
Phone Number	+61 1800-958487
Contact Person	Haylee Bosshard
Date Prepared	March 31, 2023

II. SUBJECT DEVICE

Manufacturer Name	Annalise-AI Pty Ltd
Device Name	Annalise Enterprise CTB Triage Trauma
Classification Name	Radiological computer aided triage and notification software (21CFR892.2080)
Regulatory Class	II
Product Code	QAS

III. PREDICATE DEVICE

Manufacturer Name	Infervision Medical Technology Co., Ltd.
Device Name	InferRead CT Stroke.AI
510(k) reference	K211179
Classification Name	Radiological computer aided triage and notification software (21CFR892.2080)
Regulatory Class	II
Product Code	QAS

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Annalise Enterprise CTB Triage Trauma is a software workflow tool which uses an artificial intelligence (AI) algorithm to identify suspected findings on non-contrast brain CT studies in the medical care environment. The findings identified by the device include acute subdural/ epidural hematoma, acute subarachnoid hemorrhage, intra-axial hemorrhage, and intraventricular hemorrhage.

Radiological findings are identified by the device using an AI algorithm – a convolutional neural network trained using deep-learning techniques. Images used to train the algorithm were sourced from datasets that included a range of equipment manufacturers including Toshiba, GE Medical Systems, Siemens, Philips, and Canon Medical Systems. This dataset, which contained over 200,000 CT brain imaging studies, was labelled by trained radiologists regarding the presence of the four findings of interest.

The performance of the device's AI algorithm was validated in a standalone performance evaluation, in which the case-level output from the device was compared with a reference standard ('ground truth'). This was determined by two ground truthers, with a third truther used in the event of disagreement. All truthers were US board-certified neuroradiologists.

The device interfaces with image and order management systems (such as PACS/RIS) to obtain non-contrast brain CT studies for processing by the AI algorithm. Following processing, if any of the clinical findings of interest are identified in a non-contrast brain CT study, the device provides a notification to the image and order management system for prioritization of that study in the worklist. This enables users to review the studies containing features suggestive of these clinical findings earlier than in the standard clinical workflow. It is important to note that the device will never decrease a study's existing priority in the worklist. This ensures that worklist items will never have their priorities downgraded based on AI results.

The device workflow is performed parallel to and in conjunction with the standard clinical workflow for interpretation of non-contrast brain CTs. The device is intended to aid in prioritization and triage of radiological medical images only.

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V. INDICATIONS FOR USE

The Indications for Use statement is as follows:

Intended context	*Annalise Enterprise is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings:* • *acute subdural/ epidural hematoma** • *acute subarachnoid hemorrhage** • *intra-axial hemorrhage** • *intraventricular hemorrhage** **These findings are intended to be used together as one device.* *The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage.* *The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings.* *Its results are not intended:* • *to be used on a standalone basis for clinical decision making* • *to rule out specific findings, or otherwise preclude clinical assessment of CTB studies*
Intended modality	*Annalise Enterprise identifies suspected findings in non-contrast brain CT studies.*
Intended user	*The device is intended to be used by trained clinicians who, as part of their scope of practice, are qualified to interpret brain CT studies.*
Intended patient population	*The intended population is patients who are 22 years or older.*

The Indications for Use statement of the subject device differs to the predicate device only in the clinical conditions of interest, however a standalone performance evaluation was conducted and demonstrated that the device is as safe and effective for its intended use. Both the subject and predicate device are intended for use to assist with worklist triage by providing notifications of suspected findings and their associated priority.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device was evaluated and compared to the predicate device with respect to the following characteristics:

1. Indications for Use
2. Anatomical site and modality
3. Intended user and clinical use environment
4. Technical method for notification and prioritization
5. Device input and radiological image protocol
6. System components
7. Location where results are received
8. Prioritization relationship to standard of care workflow
9. Ability to support effective triage
10. Device output and means of notification to user

The following characteristics showed a difference between the subject and predicate devices. The different characteristics include:

1. Set of findings and algorithm

The difference between the subject and predicate device is the set of findings that the subject device identifies and the underlying artificial intelligence algorithm. The performance of the subject device algorithm for each of the findings was addressed in a standalone performance evaluation and showed that the subject device is as safe and effective for its intended use as the predicate device.

VII. PERFORMANCE DATA

The following performance data have been provided to support evaluation of substantial equivalence.

A. Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005.

B. Performance Testing

Performance of the subject device was assessed in four performance studies to satisfy requirements set forth in the special controls per 21CFR892.2080. These included standalone performance and triage effectiveness evaluations.

Standalone performance was assessed via a retrospective, anonymized study of adult patient, DICOM-compliant non-contrast brain CT cases. The test dataset used during the standalone performance evaluation was newly acquired and independent from the training dataset used in model development. The standalone performance study was conducted on four independently assessed cohorts which equated to a total dataset of 1,485 cases for slice thickness ≤1.5mm (positive n=1,003 and negative n=482) and 1,878 cases for slice thickness >1.5mm & ≤5.0mm (positive n=1,257 and negative n=621), collected consecutively from five US hospital network sites.

The performance testing datasets included representation across subgroups for patient demographics (gender [female: 44.9-52.2%, male: 47.8-55.1%], age [mean: 66.5-68.0 years, min: 22, max: 99-105], ethnicity [Hispanic: 5.9-11.3%], race [White/Caucasian: 76.6-82.1%, Other: 13.6-19.3%, Unknown: 2.7-6.9%]), co-existing findings or abnormalities and technical parameters (imaging equipment make, model). The datasets included GE Healthcare, Siemens and Toshiba CT scanners for the pivotal study. Additional analyses were conducted with GE, Philips, Siemens and Toshiba scanners to demonstrate the generalizability of the device.

To determine the ground truth, each deidentified case was annotated in a blinded fashion by at least two ABR-certified and protocol-trained neuroradiologists (ground truthers), with consensus determined by two ground truthers and a third ground truther in the event of disagreement. The key results of the study are summarized in the table below.

Finding	Slice Thickness Range	Operating Point	Sensitivity % (Se) (95% CI)	Specificity % (Sp) (95% CI)
Acute subdural/ Epidural hematoma	≤1.5mm	0.060177	91.4 (88.1,94.4)	86.7 (79.6,92.9)
		0.101143	89.1 (85.5,92.4)	94.9 (89.8,99.0)
		0.135700	86.5 (82.5,90.1)	96.9 (92.9,100.0)
	>1.5mm & ≤5.0mm	0.060177	82.4 (78.6,86.1)	89.6 (83.7,94.8)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	98.0 (95.2,100.0)	89.4 (82.4,95.3)
		0.060162	93.9 (89.8,97.3)	96.5 (91.8,100.0)
		0.082652	89.8 (85.0,94.6)	100 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.020255	90.7 (86.3,95.1)	92.4 (86.7,97.1)
		0.030010	87.4 (82.4,91.8)	96.2 (92.4,99.0)
Intra-axial hemorrhage	≤1.5mm	0.322700	93.1 (90.8,95.2)	85.6 (81.1,89.6)
	>1.5mm & ≤5.0mm	0.203600	93.4 (91.3,95.1)	85.1 (80.9,88.9)
		0.322700	90.3 (87.9,92.5)	90.3 (86.8,93.8)
Intraventricular hemorrhage	≤1.5mm	0.015487	95.9 (90.4,100.0)	90.9 (84.4,97.4)
		0.051859	90.4 (83.6,97.3)	97.4 (93.5,100.0)
	>1.5mm & ≤5.0mm	0.008430	95.6 (91.2,98.9)	86.0 (78.5,92.5)
		0.015487	92.3 (86.8,96.7)	89.2 (82.8,94.6)
		0.051859	87.9 (80.2,94.5)	97.8 (94.6,100.0)

The results demonstrate the subject device establishes effective triage within a clinician's queue based on high sensitivity and specificity. Further, these results are substantially equivalent to those of the predicate device.

Triage effectiveness (turn-around time) was assessed by an internal bench study using a dataset of n=277 cases positive for any of the findings eligible for prioritization. These cases were collected from multiple data sources spanning a variety of geographical locations, patient demographics and technical characteristics. The results demonstrated a triage turn-around time of 81.6 (95% CI: 80.3 – 82.9) seconds, which is substantially equivalent to the total performance time published for the predicate device.

Therefore, the subject device has been shown to satisfy the performance requirements per 21CFR892.2080, for 'Radiological computer aided triage and notification software', by providing clinically effective triage for non-contrast brain CT studies containing features suggestive of clinical findings of interest. This data demonstrates the subject device is safe and effective for its intended use, and thereby supports substantial equivalence.

VIII. CONCLUSIONS

The subject device and the predicate device are both software only packages, devices intended to assist with worklist triage by providing notification of findings. The subject and predicate devices utilize the same principles of operation and work in parallel to the current standard of care workflow.

Both the subject and predicate devices use an artificial intelligence algorithm to identify findings in images and require the same inputs (DICOM image data) and provide the same outputs (prioritization for a medical worklist).

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Standalone performance testing and the comparison of technological characteristics with the predicate devices shows that the subject device:

- performs as intended,
- is safe and effective for its intended use, and
- is therefore substantially equivalent to the predicate device.