Circle Neurovascular Imaging, Inc
% Kyle Mayr
Official Correspondent
Circle Cardiovascular Imaging, Inc.
800 5th Ave SW
Suite 1100
Calgary, Alberta T2P 3T6
Canada

October 21, 2021

Re: K212261
Trade/Device Name: StrokeSENS LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS

Dear Kyle Mayr:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 14, 2021. Specifically, FDA is updating this SE Letter to indicate the correct official correspondent contact name and address as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica Lamb, OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-6167, jessica.lamb@fda.hhs.gov.

Sincerely,

For

Jessica Lamb
Assistant Director
Mammography Ultrasound and Imaging Software Branch
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Circle Neurovascular Imaging, Inc.
% John Smith
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

October 14, 2021

Re: K212261
Trade/Device Name: StrokeSENS LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: July 16, 2021
Received: July 20, 2021

Dear John Smith:

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,

Jessica Lamb

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212261

Device Name
StrokeSENS LVO

Indications for Use *(Describe)*
StrokeSENS LVO is a radiological computer-aided triage and notification (CADt) software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) in head CTA images.

StrokeSENS LVO uses a software algorithm to identify suspected LVO findings. In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of the existence of a suspected LVO that requires review. The notification system is intended to be used in parallel to the standard of care workflow to notify clinicians of the existence of the case earlier that they may have been notified as part of the standard of care workflow.

Notifications may include a compressed preview of images. Notifications are meant for informational purposes only and are not intended for diagnostic use beyond notification. The StrokeSENS LVO device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of StrokeSENS LVO are intended to be used in conjunction with other patient information and based on professional judgement, to assist with triage / prioritization of medical images. Notified clinicians are responsible for viewing full images per standard of care.

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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5.1 510k Summary – StrokeSENS LVO

K212261

I. SUBMITTER

Submitter's Name:	Circle Neurovascular Imaging, Inc.
Address:	Suite 1100 – 800 5th Ave SW, Calgary, AB, Canada, T2P 3T6
Date Prepared:	July 16, 2021
Telephone Number:	+1 403 338 1870
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Contact Person:	Kyle Mayr
Email:	kyle.mayr@circlecvi.com

II. DEVICE

Name of the Device:	StrokeSENS LVO
Short Brand Name:	StrokeSENS LVO
Common or Usual Name:	Medical Image Processing Software
Classification Name:	Radiological Computer-Assisted Triage And Notification Software
Proposed Classification:	Device Class II Special Controls Product Code: QAS Regulation Number: 21 CFR 892.2080

III. PREDICATE DEVICE

ContaCT, manufactured by Viz.AI (DEN170073)

IV. DEVICE DESCRIPTION

StrokeSENS LVO is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) in head CTA images. StrokeSENS LVO uses a software algorithm based on machine learning to identify suspected LVO findings. In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of the existence of a suspected LVO that requires review.

Clinical Characteristics and Procedures of Use

After a CT Angiography (CTA) head scan is performed, the images are automatically routed to StrokeSENS LVO where they are processed and analyzed for characteristics suggestive of LVO. The notification system is comprised of an on-screen notice of a suspected LVO to the user and an outbound notification to a neurovascular specialist. The notification states that a suspected LVO is present, and that the user should review the images in a diagnostic radiological viewer. In the case of a negative finding, no notification is sent, and the standard of care workflow remains in place.

Technological Characteristics

StrokeSENS LVO DICOM-compliant software system consists of two main components: 1) the StrokeSENS LVO Processing Engine and 2) a compatible Radiological Software Platform:

1. The *StrokeSENS LVO Processing Engine* is responsible for receiving, processing, and analyzing image data and communicating results. Primarily, the Processing Engine consists of a software algorithm (a sequence of instructions/operations) that is responsible for analyzing contrast-enhanced CT (CTA) image data of the head to identify characteristics that are consistent with LVO. The software algorithm is a binary classifier, providing a binary output of either positive or negative for suspected LVO, based on a pre-defined threshold. The output is returned to the Radiological Software Platform for the purposes of triage and notification. The Processing Engine is integrated into, or installed adjacent to, a compatible Radiological Software Platform.

2. The compatible *Radiological Software Platform* is configured to retrieve/receive contrast-enhanced head CT (CTA) images from the CT scanner or PACS, and automatically transmit, or make available, a copy of the image data for processing and analysis by the LVO Processing Engine. After successful processing of a case via the StrokeSENS LVO Processing Engine, the results are returned to the Radiological Software Platform for the intended purpose of triage and notification.

V. INDICATIONS FOR USE/ INTENDED USE

1. Indications for use

StrokeSENS LVO is a radiological computer-aided triage and notification (CADt) software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) in head CTA images.

StrokeSENS LVO uses a software algorithm to identify suspected LVO findings. In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of the existence of a suspected LVO that requires review. The notification system is

intended to be used in parallel to the standard of care workflow to notify clinicians of the existence of a potential LVO earlier than being notified as part of the standard of care workflow.

Notifications may include a compressed preview of images. Notifications are meant for informational purposes only and are not intended for diagnostic use beyond notification. The StrokeSENS LVO device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of StrokeSENS LVO are intended to be used in conjunction with other patient information and based on professional judgement, to assist with triage / prioritization of medical images. Notified clinicians are responsible for viewing full images per standard of care.

2. Special Conditions for Use Statement(s):

For prescription use only. US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

VI. COMPARISON WITH PREDICATE DEVICE

StrokeSENS LVO is considered to be substantially equivalent to Viz.AI: ContaCT (hereafter "ContaCT"), a commercially available device manufactured by Viz.AI, Inc. The subject and predicate devices are both radiological computer-assisted triage and notification software programs. Both devices use machine learning software implementations to analyze CTA images to aid in the prioritization, triage, and notification of suspected large vessel occlusion (LVO) cases. Both software devices notify a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis performed by the device's algorithm, in parallel to the standard of care workflow. The subject and predicate devices are similar in that neither device alters the original image database or marks up / alters the CTA input images. The subject and predicate device differ in that the subject device generates an email notification that links to the StrokeSENS platform radiological viewing software or other compatible radiological viewing software whereas the predicate generates a notification that is sent to a mobile application.

StrokeSENS LVO has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate device, with minor differences in the notification mechanism. The minor differences do not raise new questions on the safety and effectiveness of the device; therefore the subject device is as safe and effective as the predicate device. A summary substantial equivalence chart comparing the similarities and differences between the StrokeSENS LVO and its predicate device is provided below, as table 5.1-1.

Table 5.1-1. Feature comparison table of StrokeSENS LVO with the predicate device, ContaCT.

Feature / Characteristic	**Subject Device**	**Predicate Device**
General information		
Device name	StrokeSENS LVO	ContaCT

Manufacturer	Circle Neurovascular Imaging	Viz.AI
510(k) number	K212261	DEN170073
Device Class	II	II
Device classification	QAS	QAS
Regulation Name	Radiological Computer-Assisted Triage And Notification Software	Radiological Computer-Assisted Triage And Notification Software
Regulation number	21 CFR 892.2080	21 CFR 892.2080
Indications for Use / Intended Use	StrokeSENS LVO is a radiological computer-aided triage and notification (CADt) software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) in head CTA images. StrokeSENS LVO uses a software algorithm to identify suspected LVO findings. In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of the existence of a suspected LVO that requires review. The notification system is intended to be used in parallel to the standard of care workflow to notify clinicians of the existence of the case earlier that they may have been notified as part of the standard of care workflow. Notifications may include a compressed preview of images. Notifications are meant for informational purposes only and are not intended for diagnostic use beyond notification. The StrokeSENS LVO device does not alter the original medical	ContaCT is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow. ContaCT uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting, and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification. Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

	image and is not intended to be used as a diagnostic device. The results of StrokeSENS LVO are intended to be used in conjunction with other patient information and based on professional judgement, to assist with triage / prioritization of medical images. Notified clinicians are responsible for viewing full images per standard of care.	
Clinical Characteristics		
User Population	Hospital Networks and trained clinicians	Same
Clinical application/Anatomical Region	Acute Stroke / Head	Same
Relationship to standard of care workflow	In Parallel / Concurrently	Same
Technological Characteristics		
Input data type	CTA data in DICOM format (vendor independent)	CTA data in DICOM format (vendor independent)
Algorithm Implementation	Artificial Intelligence / Machine Learning Algorithms are static and locked. Algorithms are not dynamic or learning while in the market.	Same
Alteration of original image database	No	Same
Notification / Workflow	Email, Workstation, Mobile Notification message of Suspected LVO	Mobile Notification message of Suspected LVO

DICOM compliant	Yes	Same

VII. PERFORMANCE DATA

Performance validation testing and software verification and validation activities were conducted to comply with specified design requirements in accordance with applicable consensus standards and to satisfy the special controls of the device classification.

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, IEC 62366:2015 and ISO 14971:2019. DICOM conformance testing was performed to verify compliance with NEMA 3.1-3.20 (2011) standards. Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per the FDA Guidance documents “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “Content of Premarket Submission for Management of Cybersecurity in Medical Devices”. Software performance, verification and validation testing demonstrated that the StrokeSENS system met all design requirements and specifications.

To demonstrate the standalone performance of StrokeSENS LVO in accordance with the 892.2080 special controls, a retrospective case study was conducted to assess the sensitivity and specificity of StrokeSENS LVO for detecting Large Vessel Occlusion (LVO). Performance was reported on a heterogenous dataset of 400 independent studies (217 LVO cases and 183 non-LVO cases). The dataset had sufficient representation of relevant parameters such as age, sex, scanner vendor, and slice thickness. The dataset had a reasonably balanced prevalence of LVO (54.3%; 217 positive cases & 183 negative cases) and includes challenging cases (small/other occlusions and intracranial hemorrhage) that are representative of the clinical population undergoing baseline imaging for suspected acute ischemic stroke.

The StrokeSENS LVO module met the performance targets intended for the clinical performance assessment, as described in table 10.1-3. The device achieved a mean sensitivity of 89.4% CI = [85.3%, 93.5%], and mean specificity of 87.4% CI = [82.6%, 92.2%] for the binary LVO detection task on the test set (N=400, LVO=217, Non-LVO=183). In addition, an analysis of time to notify of suspicious cases was conducted by evaluating the average time for the StrokeSENS LVO device to process the CTA image and generate a notification (for LVO positive cases). The device achieved a mean value of 0.75 minutes (S.D: ±0.17 mins, Min: 0.46 mins, Max: 1.23 mins), which exceeded the goal of <5 minutes.

Table 5.1-2 LVO validation and performance test summary

Test	Acceptance Criteria	Test Results
Sensitivity	Sensitivity > 80 %	89.4%, (95% CI = 85.3, 93.5)

Specificity	Specificity > 80 %	87.4%, (95% CI = 82.6, 92.2)
Processing Time	<5 minutes	Mean: 0.75 mins S.D: ±0.17 mins Min: 0.46 mins Max: 1.23 mins

VIII. CONCLUSIONS

The information submitted in this 510k submission, including the performance testing and predicate device comparisons, support the safety and effectiveness of the StrokeSENS LVO software as compared to the predicate device: ContaCT (DEN170073).

The StrokeSENS LVO device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Performance data demonstrate that the software functions as intended. Thus, the StrokeSENS LVO device is substantially equivalent.