EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
CONTACT

DECISION SUMMARY

A. De Novo Number:

DEN170073

B. Purpose for Submission:

De novo request for evaluation of automatic class III designation for Viz.AI, ContaCT

C. Applicant:

Viz.AI

D. Proprietary and Established Names:

ContaCT

E. Regulatory Information:

1. Regulation section:

   CFR 892.2080

2. Classification:

   Class II Special Controls

3 Product code:

   QAS

4. Panel:

   90 (Radiology)

F. Indications for Use:

1. Indications for Use:

   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.

2. Special Conditions for Use Statement(s):

   For prescription use only

3. Warnings, precautions, and limitations:

   Identification of suspected findings is not for diagnostic use beyond notification.

   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.

G. Device Description:

ContaCT is a notification only, parallel workflow tool installed across the stroke network in healthcare facilities to identify and communicate images and information of specific patients to a neurovascular specialist (b) (4) patients' CT scan. As discussed below, the device facilitates a workflow parallel to the standard of care workflow, and, in the case of a true positive study, results in a notified specialist entering the standard of care workflow earlier (see **Figure 1** below).

(b) (4)

The device works in parallel to the standard of care workflow. After a CTA has been performed, a copy of the study is automatically sent to and processed by ContaCT. ContaCT performs vessel segmentation and quantifies image characteristics consistent with a Large Vessel Occlusion (LVO) in a large cerebral vessel, and sends a notification based on a fixed threshold to a neurovascular specialist, recommending review of these images. Notifications provide links to preview a compressed version of the identified study on a mobile application.

1. Description of triage and notification effects (Special Control 1.iii.)

   Depending on the results of image processing, the parallel workflow created by the device via a notification has the potential to positively impact the standard of care. Specifically, in the event of a True Positive (TP) study identified by the device, ContaCT parallel workflow allows a neurovascular specialist to become involved sooner in the workflow.

   In the event that the device identifies a False Negative (FN) case and improperly concludes a study does not contain a suspected LVO, no notification is sent and the case will be identified through the standard of care workflow without interruption.

   In the event that the device identifies a False Positive (FP), the specialist receiving the notification would preview the images and further evaluate the provided imaging on a diagnostic imaging system prior to disregarding the study, leaving the standard of care uninterrupted. The small amount of disruption to the specialist's time does not affect the patient.

   Similarly, if the device identifies a True Negative (TN) case, no notification is sent and the standard of care is uninterrupted. In all scenarios, trained radiologists read all images per standard of care, regardless of the performance of the ContaCT Device.

   In sum and as noted above, the device is intended to send notifications and non-

diagnostic images from DICOM studies so as to alert a specialist as to the timely existence of a case that may potentially benefit from that specialist's attention, who would have reviewed them at a later time, had the device not been available.

2. Technological Characteristics

ContaCT is a software only device that can be segmented into three components: (1) Image Forwarding Software, (2) Image Processing and Analysis Software, and (3) Image Viewing Software.

(1) The *Image Forwarding Software* is configured by the hospital to interact with a healthcare facility's scanner, PACS or local DICOM router and is responsible for automatically transmitting a copy of DICOM files from the local router through a secured channel to the *Image Processing and Analysis Software* based on DICOM metadata.

(2) The *Image Processing and Analysis Software* component of the device is hosted on a server and is responsible for receiving, assembling, processing, analyzing and storing DICOM images. This software component includes the software algorithm that is responsible for automatic filtering and excluding studies that are incomplete, of unacceptable technical quality, or inappropriate physiology, and identifying and quantifying image characteristics that are consistent with an LVO in acceptable studies. When the software algorithm detects imaging characteristics suggestive of a LVO, the Image Processing and Analysis Software component sends a notification to the specialist identifying the study of interest. While the software algorithm informs the notification process, no other diagnostic information is generated from the algorithm or available to the user beyond the notification.

(3) The *Image Viewing Software* component is a non-diagnostic DICOM viewing mobile application, allowing a trained clinician to view original non-contrast CT and CTA studies with basic viewing functions (scroll through a cine, adjust window level and window width, adjust MIP thickness, pan, and zoom) prior to definitive review of images on a diagnostic workstation.

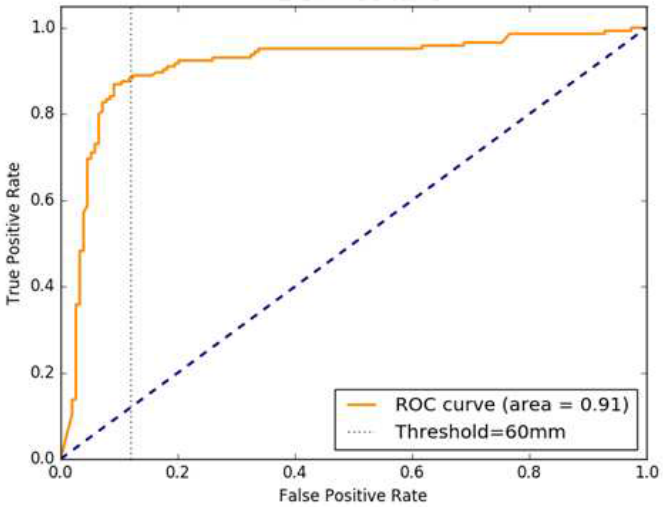
3. Software Algorithm Summary (Special Control 1.i.)

The ContaCT algorithm identifies applicable CTA series and verifies that contrast is visible in the soft matter of the brain and that no metallic artifacts such as aneurism clips are present in the soft matter of the brain. Skull stripping and registration steps are performed. The large vessels are identified and segmented, and the amount of extension of the contrast filled segments is compared to a pre-defined threshold. If the threshold exceeds the magnitude of the contrast filled segment, a notification is generated.

Training CTA studies were used from multiple facilities to develop and train the algorithm. Three algorithm training phases included: initial development and training; pre- and post- processing fine-tuning; and threshold optimization. The training cases are

(b) (4)

The following figure presents the ROC and performance curves of the algorithm in the standalone performance dataset. The estimated area under the curve (AUC) is .91; the fixed optimum threshold, 60mm, is marked with the vertical dashed line:



H. Standard/Guidance Document Referenced

NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) set. FDA recognition number 12-300.

Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005)

Guidance for Industry and Food and Drug Administration Staff: Computer -Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions (issued July 3, 2012)

I. Performance Characteristics:

The device is a software-only device. Some common performance characteristics for other device types are included below with a note that these characteristics are not applicable to this type of software-only device.

1. Biocompatibility/Materials

   Not applicable

2. Shelf Life/Sterility

   Not applicable

3. Electromagnetic Compatibility and Electrical Safety

   Not applicable

4. Magnetic Resonance (MR) Compatibility

   Not applicable

Nonclinical performance data were provided to address the following areas:

5. Software (Special Control 1.v.)

   The device is a software only device.

   Viz.AI provided software documentation at a Moderate Level of Concern according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Version: 1.0
Level of Concern: Moderate
Software Description: Viz.AI provided a general description of the features in the software documentation and in the device description. The device includes three components including image forwarding software, cloud analysis software, and mobile device notification software. The description of the software is consistent with the device functionality described in the device description.
Device Hazard Analysis: Viz.AI provided separate analyses for the backend, cloud, and mobile application. The content of the hazard analysis is sufficient and assesses pre- and post- mitigation risks. The device hazard analysis includes: • identification of the hazardous event • severity of the hazard

• probability of the hazard • cause(s) of the hazard • method of control or mitigation • corrective measures taken, including an explanation of the aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event • verification of the control implementation is traceable through the enumerated traceability matrix
Software Requirement Specifications (SRS): The SRS includes documents for the backend and mobile platforms. Each document includes user, engineering, algorithmic, cybersecurity, and various other types of requirements that give a full description of the functionality of the device. The SRS is consistent with the device description and software description.
Architecture Design Chart: The architecture design chart provides the software overview and includes flow diagrams representative of process flow for various features of the ContaCT software.
Software Design Specification: Page 43 Section E. The SDS is traceable to the SRS and demonstrates how individual requirements are implemented in the software design and includes appropriate linkages to predefined verification testing.
Traceability Analysis/Matrix: Viz.AI provided traceability between all documents including the SRS, SDS, and subsequent Verification and Validation. Hazards Mitigations are traceable throughout all documents.
Software Development Environment: Viz.AI outlined the software development environment and the processes/procedures used for medical device software development. The content is consistent with expected quality system norms.
Verification and Validation Testing: The validation and system level verifications procedures are based upon the requirements with clearly defined test procedures and pass/fail criteria. All tests passed. Unit level test procedures, actual, and expected results are included for all design specifications. V&V testing included systems to ensure that input images meet input specification ranges.
Revision Level History: This is the initial version 1.0 for the device. The standalone testing study was completed with this version of the device.
Unresolved Anomalies: Viz.AI stated that there are no unresolved anomalies.
Cybersecurity: The cybersecurity documentation is consistent with the recommendations for information that should be included in premarket submissions outlined in the FDA guidance document Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (issued October 2, 2014). Information related to cybersecurity reviewed included: Hazard analysis related to cybersecurity risks, traceability documentation linking cybersecurity controls to risks considered, summary plan for validating software updates and patches throughout the lifecycle of the medical device, summary describing controls in place to ensure that the medical device will maintain its integrity, and device instructions for use and product specifications related to recommended cybersecurity controls appropriate for the intended use of the device.

6. Standalone Performance Testing Protocols and Results (Special Control 1.iv.)

Viz.AI conducted a retrospective study to assess the sensitivity and specificity of the image analysis algorithm and notification functionality of ContaCT against a ground truth as established by trained neuro-radiologists in the detection of large vessel occlusions (LVO) in the brain, and to compare the Standard of Care with ContaCT on CTA-to-notification time.

a. Data Characteristics (Special Control 1.ii.)

Three hundred (300) CT angiogram (CTA) images (studies) were obtained from two clinical sites in the U.S. There were approximately equal numbers of positive and negative cases (images with LVO and without LVO, respectively) included in the analysis.

Inclusion Criteria:

- The patient is older than 22 years of age when presenting to the healthcare facility;
- The images were from patients who underwent a stroke protocol assessment; and
- Received a head and neck CTA.

Exclusion Criteria:

Series used to identify potential LVOs were axial thin slice CTAs. CTA series may have been excluded because of insufficient technical quality. Exclusion criteria included:

- Series containing metal artifacts in the soft matter of the brain;
- Series that are non-axial;
- Series containing missing slices;
- Series displaying no visible contrast due to bad bolus timing during the series acquisition process;
- Series containing inconsistent pixel spacing;
- Series containing slices thicker than 0.625mm;
- Series containing improperly ordered slices (e.g. as a result of manual correction by an Imaging technician); and
- Series containing an incomplete skull.

b. Test Protocol

All 300 studies were reviewed by neuro-radiologists to establish the Ground Truth; each study was reviewed to determine if the image contained image features consistent with an LVO, and thus required further review. In cases where the neuro-radiologists did not agree on whether a study required further review, an additional

neuro-radiologist provided an additional opinion and established a ground truth by majority consensus.

Each study was forwarded to the ContaCT device, and then processed and analyzed. When ContaCT identified a suspected LVO in a test study, it sent a notification to the mobile application component recommending further review of the study. A log of notifications was maintained by the testing facility and compared with respect to the Ground Truth for each case. Each case was classified based on the following table:

		Device Output (Recommends Urgent Review)	
		Yes	No
Ground Truth (Emergent Review Recommended)	Yes	True Positive (TP)	False Negative (FN)
	No	False Positive (FP)	True Negative (TN)

c. Endpoints

Primary Analysis: Sensitivity and Specificity

The sensitivity and specificity of the device performance were calculated using two-sided 95% Clopper-Pearson confidence intervals and compared to pre-defined performance goals.

Sensitivity was calculated as follows: TP / (TP+FN)

Specificity was calculated as follows: TN / (TN+FP)

Study endpoints and performance goals:

(b) (4)

Secondary Analysis: CTA-to-Notification Time

As a secondary analysis, the company compared the Standard of Care CTA-to-notification time with the equivalent metric observed for ContaCT.

In standard clinical practice, a final radiology report is produced following dictation, review, and signoff of that report by the attending radiologist responsible for reviewing the study. Then, the referring physician or a neuro-interventional specialist is typically verbally notified by the attending radiologist of findings that require urgent review. Following this verbal notification, the radiologist completes his or her review of the images and completes a full radiologist report, in which they document the time that they notified the responsible doctor. The time of the specialist notification was used as the Standard of Care time-to-notification in this analysis.

ContaCT's time-to-notification of potentially concerning findings is directly analogous to this Standard of Care metric.

d. Test Results

Sensitivity and Specificity

Sensitivity and specificity were calculated comparing the ContaCT's output to the Ground Truth as established by trained neuro-radiologists. Sensitivity and specificity were 87.8% (95% CI: 81.2% - 92.5%) and 89.6% (95% CI: 83.7% - 93.9%), respectively. (b) (4)

Furthermore, the area under the receiver operating characteristic curve (ROC) was 0.91, demonstrating the clinical utility and ability of the device to effectively triage based on the imaging study results.

Time-to-Notification

The ContaCT CTA-to-notification time was documented for all 300 cases. The Standard of Care CTA-to-notification time was available in 85 reports of these 300 cases. Of these 85 cases, 44 were true positives, i.e. identified by both ContaCT and the ground truth as LVO positive. The Standard of Care times, ContaCT notification times, and differences on those 44 cases that were also identified by ContaCT are reported below.

As shown in the table below, in these reports, the average and median CTA-to-notification times were 58.72 minutes and 51.50 minutes, respectively, for the Standard of Care (two-sided 95% confidence interval for the mean: [46.21, 71.23]. The average and median CTA-to-notification times were 7.32 minutes and 5.60 minutes, respectively, for ContaCT (two-sided 95% confidence interval for the mean: [5.51, 9.13]). The mean and median difference in reporting times was 51.40 minutes and 44.78 minutes, respectively (two sided 95% confidence interval of the mean difference [36.32, 58.72]). In 42 of the 44 studies (95.5%), the notification from ContaCT arrived earlier than the Standard of Care [range: 6.1 - 206.4 minutes earlier]. The total range of observed per-study differences was -12.7 minutes to 206.4 minutes. Thus, ContaCT tends to substantially shorten the time to notifying the specialist for LVO cases as compared with the Standard of Care.

The ContaCT time-to-notification consists almost entirely of the time the device takes to process the data and produce a result. Notifying the specialist of the device result takes mere seconds. Standard of Care time-to-notification consisted of the time from the initial scan of the patient to when the radiologist reviews the images, identifies the urgent finding, in this case a LVO, and pages or phones the responsible specialist to relate the findings verbally prior to generating a study report.

Standard of Care (N=44)	**Time to Notification of Specialist for LVO cases (mins)**
Average [95%CI]	58.72 [46.21, 71.23]
Median	51.50
Standard Deviation	41.14

Standard of Care Time to Notification for LVO cases: *This Standard of Care real-world data was collected from radiology reports that documented the time the radiologist notified the specialist of a critical finding (an LVO) during a wet read and compared to the timestamp from when the CTA was completed to generate a standard of care Time to Notification of Specialist.*

Viz ContaCT (N=44)	**Time to Notification of Specialist for LVO cases (mins)**
Average [95%CI]	7.32 [5.51, 9.13]
Median	5.60
Standard Deviation	5.95

Viz ContaCT Time to Notification of Specialist for LVO cases: *This data was collected during the standalone performance testing of the ContaCT device.*

Real World Evidence

Real world evidence from literature suggests that there is a patient benefit associated with earlier involvement of the neurovascular specialist in the treatment of LVOs.[(1)] Endovascular therapy is highly time-critical,[(2)] with each minute saved in onset-to-treatment time resulting in an average 4.2 days of extra healthy life.[(3)] Meretoja et al. notes that small reductions in endovascular delays lead to marked health benefits over patients' lifetimes and that services should be optimized to reduce delays to endovascular therapy.[(3)] It is well known that the neurovascular specialist plays a critical role in the management of LVO patients and that earlier involvement of the neurovascular specialist clearly benefits LVO patients.

ContaCT is designed to facilitate the involvement of a neurovascular specialist sooner in the process of reviewing images for suspected LVOs. Literature suggests that the time from initial presentation to eventual reperfusion is lengthy. Specifically, median onset-to-revascularization time has been reported as 202.0 minutes for direct to interventional centers, and 311.5 minutes for patients that initially presented to a non-interventional center.[4] Part of that time is the time-from-initial-CTA-scan to the time-that-the-neurovascular-specialist-is-notified-of-a-possible-LVO (the CTA to-notification time), which is the part of the workflow where the Viz.ai software would be utilized. Sun CH et al. break down the relevant time periods demonstrating an initial CT to CSC (Comprehensive Stroke Center) notification time per standard of care of >60 minutes.[5]

This is similar to *Time to Notification of Specialist for LVO cases (mins)* reported above.

1) Goyal, M., Menon, B. K., van Zwam, W. H., Dippel, D. W. J., Mitchell, P. J., Demchuk, A. M., … Jovin, T. G. (2017). Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. The Lancet, 387(10029), 1723–1731.

2) Fransen PS, Berkhemer OA, Lingsma HF, et al. Time to reperfusion and treatment effect for acute ischemic stroke: a randomized clinical trial. JAMA Neurol 2016;73:190–196.

3) Meretoja, A., Keshtkaran, M., Tatlisumak, T., Donnan, G. A., & Churilov, L. (2017). Endovascular therapy for ischemic stroke. *Neurology*, *88*(22), 2123 LP-2127.

4) Froehler, M. T., Saver, J. L., Zaidat, O. O., Jahan, R., Aziz-Sultan, M. A., Klucznick, R. P., Mueller-Kronast, N. H. (2017). Interhospital Transfer Prior to Thrombectomy is Associated with Delayed Treatment and Worse Outcome in the STRATIS Registry. *Circulation*.

5) Sun, C.-H. J., Nogueira, R. G., Glenn, B. A., Connelly, K., Zimmermann, S., Anda, K., et al. (2013). "Picture to Puncture" *Circulation*.

Conclusion (Special Control 1.iii.)

The primary endpoints of sensitivity and specificity exceeded (b) (4) . Specifically, sensitivity was observed to be 87.8% with 95% confidence interval (CI) 81.2-92.5%. Specificity was observed to be 89.6% with 95% CI 83.7-93.9%. (b) (4)

In addition, the secondary time-to-notification analysis demonstrated that CTA-to-notification time was longer for the Standard of Care than ContaCT. The mean difference of 51.40 minutes was statistically significant and quantifies effective triage for true positive LVO positive cases for this device. The difference in any individual will vary. The mean difference in this study may involve some bias because the analysis could only be done on the subset of true positive LVO cases with Standard of Care notification times. However, the large mean difference of 51.40 minutes in this subset can be assumed to overwhelm any such bias such that statistical significance would likely be retained were an analysis of all true positive LVO cases been possible.

These data and real world evidence, in combination, establish effective triage for the image analysis algorithm and notification functionality of the ContaCT device as compared to the Standard of Care. The evidence demonstrates that specialists may have the opportunity to become involved in the clinical workflow substantially earlier with notifications from the ContaCT software.

7. Animal and/or Cadaver Testing

None provided.

J. Summary of Clinical Information

Viz.AI didn't conduct a clinical reader study for the underlying CAD as the device doesn't have diagnostic outputs other than the notification. Please refer to the standalone performance testing above for Clinical Information.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 801, including 21 CFR Part 801.109 for prescription devices, and the special controls for this device type. The ContaCT User Manual provides the detailed instructions for use (Special Control 2) Other elements of the labeling for ContaCT related to the special controls for this device type are noted below.

1. Indicated patient population (Special Control 2.i.)

ContaCT is indicated for patients older than 22 years of age. Additionally, the patient should have undergone a stroke protocol assessment after presenting to the Healthcare Facility and receive a head and neck CT angiogram (CTA) during their stroke protocol assessment.

2. Indicated User population (Special Control 2.ii.)

The ContaCT mobile application is intended to be used by neurovascular specialists, such as vascular neurologists, neuro-interventional specialists, or users with similar training who have been pre-authorized by their Healthcare Organization or Facility.

3. Device Limitations (Special Control 2.iii.)

Identification of suspected findings is not for diagnostic use beyond notification. 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.

4. Compatible Hardware (Special Control 2.iv.)

   Recommended CTA acquisition parameters and exclusion parameters are included in the labeling.

5. Device Instructions (Special Control 2.v.)

   Adequate instructions for use are provided in the user's manual for ContaCT.

6. Performance Testing Summary (Special Control 2.vi.)

   Standalone performance testing protocols, device performance, algorithm summary, and algorithm performance are included in Appendices in the user manual. The algorithm performance is reported along with the ROC curve.

L. Identified Risks to Health and Mitigation Measures

Identified Risks	Mitigation Measures
Failure to prioritize images for review with positive findings may result in incorrect and/or delayed patient management	Certain design verification and validation activities identified in special control (1) Certain labeling information identified in special control (2)
Positive notifications may result in deprioritization of review of images from other patients.	Certain design verification and validation activities identified in special control (1) Certain labeling information identified in special control (2)
The device could be misused to analyze images from an unintended patient population or on images acquired with incompatible imaging hardware or incompatible image acquisition parameters, leading to inappropriate notifications being displayed to the user.	Certain design verification and validation activities identified in special control (1) Certain labeling information identified in special control (2)
Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment.	Certain design verification and validation activities identified in special control (1) Certain labeling information identified in special control (2)
The triage and notification outputs of the device are inappropriately used for primary interpretation or	Certain design verification and validation activities identified in special control (1)

as an adjunct for diagnosis outside the intended use of the device.	Certain labeling information identified in special control (2)

M. Benefit/Risk Determination

Summary	
Summary of the Benefit(s)	In Viz.AI's study the average and median CTA-to-notification times were 58.72 minutes and 51.50 minutes, respectively, for the Standard of Care (two-sided 95% confidence interval for the mean: [46.21, 71.23]. The average and median CTA-to-notification times were 7.32 minutes and 5.60 minutes, respectively, for ContaCT (two-sided 95% confidence interval for the mean: [5.51, 9.13]). This is also lower than the average time to notification of 66 minutes reported in literature for LVO's diagnosed with CT Angiogram. The notification is informed by the software algorithm with a sensitivity and specificity are 87.8% (81.2% - 92.5%) and 89.6% (83.7% - 93.9%), respectively. The clinical benefit is that the device identifies patients who may benefit from rapid intervention by a neurovascular specialist. The clinical benefit is that a patient may be eligible for use of mechanical thrombectomy and/or tPA administration. By using one or both of these techniques, a substantial relative volume of brain may be able to be saved by timely intervention. From an overall US public health perspective, by treating ischemic stroke of large vessels more aggressively, as is now done for acute coronary artery occlusion, the resulting amount of disability from ischemic stroke, which remains a major cause of US disability in both men and women can potentially be significantly decreased.
Summary of the Risk(s)	There are no major risks for the device because the device operates in parallel to the current usual standard of care. Minor risks include: • Failure to prioritize images for review with positive findings may result in incorrect and/or delayed patient management. • Positive notifications may result in deprioritisation of review of images from other patients. • The device could be misused to analyse images from an unintended patient population or on images acquired with incompatible imaging hardware or incompatible image acquisition parameters, leading to inappropriate notifications being displayed to the user. • Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment. • The triage and notification outputs of the device are inappropriately used for primary interpretation or as an adjunct for diagnosis outside the intended use of the device.

Summary of Other Factors	The device only notifies the neurovascular specialist. Beyond that it is up the regional healthcare delivery system to get the patient the neurovascular specialist in the neurovascular interventional suite/operating room. If adequately treated in time the patient will have no residual neurological deficit. In some cases there may be a small residual neurological deficit. If the disease is untreated, there may be loss of speech, recognition of words, movement of the arms and/or legs, normal bowel and bladder control, or other neurologic functions resulting potentially in long term disability.
Conclusions Do the probable benefits outweigh the probable risks?	Yes. The benefit of ContaCT, namely, early identification and notification of a specialist significantly outweighs the minimal risk of a small amount of the specialists time needed to review and disregard a false positive. In the case of a false negative, the standard of care workflow prevails, so there is no risk compared to standard of care for the patient. In general, there is no direct risk to the patient as this is a notification only, software only device. There are no significant risks which have not been mitigated via clinical testing and labelling. Therefore, given the available information concerning the benefits, risks, and supporting data, the probable benefits for the device outweighs the probable risks, given the combination of general controls and special controls established for this device.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

N. Conclusion

The information provided in this de novo submission is sufficient to classify this device into class II under regulation 21 CFR 892.2080. FDA believes that the stated special controls, in combination with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type. The device is classified under the following:

Product Code: QAS

Device Type: Radiological computer aided triage and notification software.

Class: II (special controls)

Regulation: 21 CFR 892.2080

(a) *Identification*. Radiological computer aided triage and notification software is an image processing prescription device intended to aid in prioritization and triage of radiological medical images. The device notifies a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis of those images performed by the device. The device does not mark, highlight, or direct users' attention to a specific location in the

original image. The device does not remove cases from a reading queue. The device operates in parallel with the standard of care, which remains the default option for all cases.

(b) *Classification*. Class II (Special Controls). Radiological computer aided triage and notification software must comply with the following special controls:

1. Design verification and validation must include:

    i. A detailed description of the notification and triage algorithms and all underlying image analysis algorithms including, but not limited to, a detailed description of the algorithm inputs and outputs, each major component or block, how the algorithm affects or relates to clinical practice or patient care, and any algorithm limitations.

    ii. A detailed description of pre-specified performance testing protocols and dataset(s) used to assess whether the device will provide effective triage (e.g., improved time to review of prioritized images for pre-specified clinicians).

    iii. Results from performance testing that demonstrate that the device will provide effective triage. The performance assessment must be based on an appropriate measure to estimate the clinical effectiveness. The test dataset must contain sufficient numbers of cases from important cohorts (e.g., subsets defined by clinically relevant confounders, effect modifiers, associated diseases, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals for these individual subsets can be characterized with the device for the intended use population and imaging equipment.

    iv. Standalone performance testing protocols and results of the device.

    v. Appropriate software documentation (e.g., device hazard analysis; software requirements specification document; software design specification document; traceability analysis; description of verification and validation activities including system level test protocol, pass/fail criteria, and results).

2. Labeling must include the following:

    i. A detailed description of the patient population for which the device is indicated for use.

    ii. A detailed description of the intended user and user training that addresses appropriate use protocols for the device.

iii. Discussion of warnings, precautions, and limitations must include situations in which the device may fail or may not operate at its expected performance level (e.g., poor image quality for certain subpopulations), as applicable

iv. A detailed description of compatible imaging hardware, imaging protocols, and requirements for input images.

v. Device operating instructions.

vi. A detailed summary of the performance testing, including: test methods, dataset characteristics, triage effectiveness (e.g., improved time to review of prioritized images for pre-specified clinicians), diagnostic accuracy of algorithms informing triage decision, and results with associated statistical uncertainty (e.g., confidence intervals), including a summary of sub-analyses on case distributions stratified by relevant confounders, such as lesion and organ characteristics, disease stages, and imaging equipment.