



January 13, 2020

Viz.AI, Inc.
% John Smith
Partner
Hogan Lovells US LLP
555 13th St. NW
WASHINGTON DC 20004

Re: DEN170073

Trade/Device Name: ContaCT
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage and Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: September 29, 2017
Received: September 29, 2017

Dear John Smith:

This letter corrects our classification order dated February 13, 2018. We have made several minor changes to the language used to describe the special controls that, in combination with general controls, provide reasonable assurance of safety and effectiveness for this device type. These changes do not substantively alter the nature of the special controls but rather, are intended to provide additional clarity and promote overall consistency in how special controls are described.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ContaCT, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ContaCT, and substantially equivalent devices of this generic type, into Class II under the generic name Radiological Computer Aided Triage and Notification Software.

FDA identifies this generic type of device as: **Radiological computer aided triage and notification software.**

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On September 29, 2017, FDA received your De Novo requesting classification of the ContaCT. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ContaCT into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the ContaCT can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	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 as an adjunct for diagnosis outside the intended use of the device.	Certain design verification and validation activities identified in special control (1) Certain labeling information identified in special control (2)

In combination with the general controls of the FD&C Act, Radiological Computer Aided Triage and Notification Software is subject to the following special controls:

Special Controls
<p>(1) Design verification and validation must include:</p> <ul style="list-style-type: none"> (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.

Special Controls

- (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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Radiological Computer Aided Triage and Notification Software they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Alex Cadotte at 240-402-4871.

Sincerely,

Robert Ochs, Ph.D.
Deputy Director for Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health