August 3, 2023

Viz.ai, Inc.
Gregory Ramina
Director of Regulatory Affairs
201 Mission St., 12th Floor
San Francisco, California 94105

Re: DEN230003
Trade/Device Name: Viz HCM
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular machine learning-based notification software
Regulatory Class: Class II
Product Code: QXO
Dated: January 9, 2023
Received: January 10, 2023

Dear Gregory Ramina:

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 Viz HCM, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Viz HCM is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG made on compatible ECG devices. Viz HCM is capable of analyzing the ECG, detecting signs associated with hypertrophic cardiomyopathy (HCM), and allowing the user to view the ECG and analysis results. Viz HCM is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older. Viz HCM is not intended for use on patients with implanted pacemakers.
>
> Viz HCM is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz HCM identifies patients for further HCM follow-up and does not replace the current standard of care methods for diagnosis of HCM. The results of the device are not intended to rule-out HCM follow-up.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Viz HCM, and substantially equivalent devices of this generic type, into Class II under the generic name Cardiovascular machine learning-based notification software.

FDA identifies this generic type of device as:

> **Cardiovascular machine learning-based notification software.** Cardiovascular machine learning-based notification software employs machine learning techniques to suggest the likelihood of a cardiovascular disease or condition for further referral or diagnostic follow-up. The software identifies a single condition based on one or more non-invasive physiological inputs as part of routine medical care. It is intended as the basis for further testing and is not intended to provide diagnostic quality output. It is not intended to identify or detect arrhythmias.

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 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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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 announcing the classification.

On January 10, 2023, FDA received your De Novo requesting classification of the Viz HCM. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Viz HCM 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 Viz HCM 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 to health are shown in the table below. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
False positive or false negative leading to incorrect treatment or diagnosis	Clinical performance testing Non-clinical performance testing Labeling
Incorrect treatment or diagnosis due to model bias or failure to adequately generalize to the intended use population	Clinical performance testing Labeling
Device used in unsupported patient population or with unsupported input/hardware	Labeling Human factors assessment Software verification, validation, and hazard analysis
Overreliance on device output for follow-up	Human factors assessment Labeling

In combination with the general controls of the FD&C Act, Cardiovascular machine learning-based notification software is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be met:
  (i) Clinical validation must use a test dataset of real-world data acquired from a representative patient population. Data must be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment. The test dataset must be independent from data used in training/development and contain sufficient numbers of cases from important cohorts (e.g., demographic populations, subsets defined by clinically relevant confounders, comorbidities, and subsets defined by hardware and acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and acquisition systems (e.g., acquisition hardware or preprocessing software). Study protocols must include a description of the adjudication process(es) for determining ground truth of training and test datasets;
  (ii) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output over the full range of inputs;
  (iii) Performance goals used to determine success of clinical validation must be justified in the context of risks associated with follow-up testing;
  (iv) Objective performance measures (e.g., sensitivity, specificity, positive predictive value or negative predictive value) must be reported with relevant descriptive or developmental performance measures. Summary level demographic information and sub-group analyses must be provided for each study site, relevant demographic sub-groups, and acquisition systems; and
  (v) The test dataset must include a minimum of 3 geographically diverse sites, separate from sites used in training of the model.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include:
  (i) A description of the model/algorithm, algorithm inputs/outputs, and supported patient population;
  (ii) Integration testing in the intended software system or software environment; and
  (iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications, including:
    (A) A description of input signal / data quality control measures; and
    (B) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(3) Human factors assessment of the intended users in the intended use environment must evaluate the risk of misinterpretation of device output.

(4) Labeling must include:
  (i) A summary of the performance testing methods, tested hardware, tested/supported patient population, results of the performance testing for tested performance measures/metrics,

summary-level descriptions of patient demographics and associated subgroup analyses for training and test datasets, and the expected minimum performance of the device;
(ii) Device limitations or subpopulations for which the device may not perform as expected;
(iii) Warning that the user should not rely on the lack of a suspected finding to rule-out follow-up;
(iv) A statement that the device output should not replace a full clinical evaluation of the patient and that the output may not be sufficient as the sole basis for further testing;
(v) Warnings identifying sensor acquisition factors that may impact measurement results;
(vi) Guidance for interpretation of the measurements and typical follow-up testing; and
(vii) The type(s) of hardware sensor data used, including specification of compatible sensors for data acquisition.

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 Cardiovascular machine learning-based 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) for devices or postmarket 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 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/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).

If you have any questions concerning the contents of the letter, please contact Luke Ralston at 301-796-6362.

Sincerely,

Hetal B. Odobasic -S

for

Bram Zuckerman, M.D.
Director
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health