February 11, 2026

Ultrasound AI
℅ Raymond Kelly
Consultant
Arazy Group Consultants Inc.
3422 Leonardo Lane
NEW SMYRNA FL 32168

Re: DEN250007
Trade/Device Name: Delivery Date AI
Regulation Number: 21 CFR 892.8200
Regulation Name: Radiological software system for delivery date prediction
Regulatory Class: Class II
Product Code: SHE
Dated: February 28, 2025
Received: March 17, 2025

Dear Raymond Kelly:

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 Delivery Date AI, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Delivery Date AI is a post-processing software designed to analyze pregnancy ultrasound images using machine learning techniques. It analyzes raw images to provide healthcare practitioners (HCPs) with a Predicted Delivery Date (PDD) in women without a reliable estimated delivery date.
>
> The software estimates the predicted delivery date for a singleton pregnancy and should be used as an aid in clinical judgment, alongside standard methods for assessing gestational age. This is a prediction of the actual delivery date called the Predicted Delivery Date (PDD).
>
> The software processes entire images, which include fetal and maternal characteristics, and targets a specific patient population consisting of women 18 years of age or older with a singleton pregnancy at or beyond 14 0/7 weeks through 36 6/7 weeks gestation who lack a reliable Estimated Delivery Date (EDD) due to:
>
> - Unreliable LMP: Examples include irregular menstrual cycles, spotting mistaken for menses, or recent use of hormonal contraceptives.
> - No First-Trimester Ultrasound: Absence of an ultrasound before 14 weeks gestation, precluding crown-rump length measurement.

- Gestational Age Confirmation: Pregnancy within the indicated range verified by clinical indicators such as fundal height or detection of a fetal heartbeat.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Delivery Date AI, and substantially equivalent devices of this generic type, into Class II under the generic name radiological software system for delivery date prediction.

FDA identifies this generic type of device as:

> **Radiological software system for delivery date prediction**. A radiological software system for delivery date prediction is a software-only device that analyzes obstetric radiological images to predict the delivery date of a pregnancy. The device output does not replace a clinician's review or judgment on the progression of a pregnancy and should be used in conjunction with other clinical and diagnostic findings. The device does not identify at-risk pregnancies or identify specific complications.

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 March 17, 2025, FDA received your De Novo requesting classification of the Delivery Date AI. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Delivery Date AI 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 Delivery Date AI 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:

Risks to Health	**Mitigation Measures**
Inappropriate patient management due to inaccurate prediction of actual delivery date, whether significantly early or late	Clinical performance testing Software verification, validation, and hazard analysis Labeling

Risks to Health	Mitigation Measures
	Postmarket monitoring plan
Inappropriate patient management resulting from inconsistent device output due to differences in acquisitions, equipment settings, and other image input characteristics	Clinical performance testing Software verification, validation, and hazard analysis Labeling Postmarket monitoring plan
User misinterpretation of the device's output as being directly reflective of the gestational age of the fetus, contributing to: - Inappropriate patient management - Overreliance on device output	Labeling Device Characteristics

In combination with the general controls of the FD&C Act, the radiological software system for delivery date prediction is subject to the following special controls:

(1) Data obtained from clinical performance validation testing acquired under anticipated conditions of use must demonstrate that the device performs as intended when used in the intended patient population. Documentation must include the following:
   (i) A clear description of the patient population the device is intended to analyze.
   (ii) A clear description of the clinical environment and context of use in which the device is intended to be used.
   (iii) A description of the dataset(s) used, including detailed annotation methods and important cohorts (e.g., subsets defined by patient demographics, clinically relevant confounders, and image acquisition characteristics). Validation must contain a sufficient number of cases from important cohorts (i.e., subsets defined by clinically relevant demographics, confounders, effect modifiers, concomitant diseases, challenging cases, and subsets defined by image 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 imaging equipment. The test dataset must be independent of the data used in the training/development of the device.
   (iv) A description of prespecified performance testing protocols (including but not limited to the study objectives, study endpoints, statistical hypotheses, performance goals, sample size calculation, and statistical analyses). Performance goals used to determine success of the clinical validation study must be clinically justified and must be based on appropriate objective performance measures comparing the device output to known delivery information on sampled patients (e.g., Bland-Altman plots, error metrics).
   (v) Performance testing should capture inter- and intra- patient variability and ranges of agreement between the device predictions and reference standard, as well as other relevant sources of variation.

(2) Device design characteristics must ensure that information and limitations in special control (4)(i) and 4(vii) are featured in the software user interface.

(3) Software verification, validation, and hazard analysis must be provided. Software documentation must include a detailed technical description of all image analysis algorithms, including the algorithm inputs and outputs, each major component or block, and any algorithm limitations.

(4) Labeling must include:
- (i) A description of the meaning of the date predicted by the device and the relationship of the date to other calculated dates used in clinical practice (e.g., estimated delivery date);
- (ii) A description of the intended patient population, the intended user, clinical environment, and context of use, including information on interpretation of outputs within the intended clinical workflow;
- (iii) A description of the device inputs and outputs;
- (iv) A description of compatible imaging hardware and imaging protocols;
- (v) A summary of the development data and clinical validation data, including sources of data, study sites, samples sizes, demographics and other relevant characteristics of the study participants;
- (vi) A summary of performance testing including test methods, dataset characteristics, reference standard, testing environment, results (with confidence intervals), and a summary of clinical performance for all demographic subgroups and relevant confounders from testing dataset(s);
- (vii) Limiting statements that indicate:
  - (A) The output is not intended to predict or assess the risk of pre-term birth;
  - (B) A description of situations in which the device may fail or may not operate at its expected performance level (e.g., poor image quality or for certain subpopulations), as applicable; and
  - (C) A warning that users should use the device in conjunction with other clinical and diagnostic findings, including information obtained by alternative methods and clinical evaluation, as appropriate.

(5) The device manufacturer must develop and implement a post-market performance management plan that ensures regular assessment of the generalizability and device performance in the intended patient population in real-world use. The plan must include:
- (i) Data collection, analysis methods, and procedures for:
  - (A) Monitoring relevant performance characteristics and detecting changes in performance;
  - (B) Identifying sources of performance changes between validation and real-world environment over time; and
  - (C) Assessing the results from the performance testing on safety and effectiveness;
- (ii) Procedures for communicating the device's current performance to the users.

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 radiological software system for delivery date prediction 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 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 Management System Regulation (QMSR) (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).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Samuel Fielden at 301-796-6964.

Sincerely,

Laurel Burk, Ph.D.
Director
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