



October 31, 2025

Pulsenmore Ltd.
Israel Citron
Vice President QA/RA
8 Omarim St.
Omer, Darom 8496500
ISRAEL

Re: DEN240074

Trade/Device Name: Pulsenmore ES
Regulation Number: 21 CFR 892.1590
Regulation Name: Ultrasound imaging system for acquiring images at home by lay users
Regulatory Class: Class II
Product Code: SGJ
Dated: December 8, 2024
Received: December 11, 2024

Dear Israel Citron:

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

The Pulsenmore ES ultrasound system is intended to enable the acquisition of ultrasound images that allow interpreting healthcare providers to determine fetal heart rate.

The Pulsenmore ES Ultrasound System is intended for limited diagnostic ultrasound imaging in B-Mode and M-Mode in Fetal/Obstetric applications, when traditional scanning at a health clinic is impractical or when the use of telehealth (clinician-guided mode) or software-guided self-scanning (App-guided mode) is in the best interests of the patient.

The device is intended to be used by pregnant women with a singleton pregnancy at the gestational age of 14-38 weeks, when clinically indicated to determine the heart rate on the order of a physician in non-clinical environments. When directed by their physician, the patient can either follow the steps specified by the ES software application (app-guided mode) or under the direction of a healthcare professional (clinician-guided mode).

A physician interprets the images acquired with the device in a remote access setup. Access to the device operation must be granted by healthcare professionals.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Pulsenmore ES, and substantially equivalent devices of this generic type, into Class II under the generic name ultrasound imaging system for acquiring images at home by lay users.

FDA identifies this generic type of device as:

Ultrasound imaging system for acquiring images at home by lay users. An ultrasound imaging system for acquiring images at home by lay users is a prescription home use device that may consist of hardware and/or software intended for acquiring ultrasound images for interpretation by a qualified health care professional (e.g., fetal images for determination of fetal heart rate). The device provides guidance to lay users to aid image acquisition.

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 December 11, 2024, FDA received your De Novo requesting classification of the Pulsenmore ES. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Pulsenmore ES 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 Pulsenmore ES 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
Device malfunction/failure leading to injury to user (e.g., shock, burn)	Non-clinical performance testing Electrical, mechanical and thermal safety testing Electromagnetic compatibility (EMC) testing Technological characteristics Software verification, validation and hazard analysis Labeling
Poor image quality or failure to obtain adequate scan by lay user, leading to incorrect interpretation	Clinical performance testing Non-clinical performance testing Technological characteristics

or misinterpretation of device output and inappropriate patient management or delayed care	Software verification, validation and hazard analysis Human factors assessment Training Labeling
Unnecessary ultrasound exposure leading to patient injury	Non-clinical performance testing Technological characteristics Training Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the ultrasound imaging system for acquiring images at home by lay users is subject to the following special controls:

- (1) Clinical performance testing of software with representative compatible hardware must demonstrate that the device system performs as intended under anticipated conditions of use in the intended patient population. Testing must include the following:
 - (i) An evaluation of device performance in a representative user and patient population;
 - (ii) An evaluation of the diagnostic utility and quality of images/data acquired using the device;
 - (iii) Results comparing device performance to a clinically justified clinical comparator with established clinical performance; and
 - (iv) An evaluation of all adverse events.
- (2) Non-clinical performance testing must demonstrate that the device system and its components perform as intended under anticipated conditions of use. Testing must include the following:
 - (i) Validation of pre-acquisition quality control checks by software;
 - (ii) Evaluation of the function of device software and hardware control safety features;
 - (iii) Validation of device system guidance functionality in a simulated use environment;
 - (iv) For ultrasound hardware, testing including:
 - (A) Acoustic output measurement;
 - (B) Image quality evaluation; and
 - (C) Clinical measurement accuracy.
- (3) Performance testing must demonstrate the electromagnetic compatibility (EMC), electrical safety, thermal safety, mechanical safety, and wireless coexistence of the device system hardware in the intended use environment.
- (4) Performance testing must validate the reprocessing instructions for reusable components of the device system hardware.
- (5) Performance testing must demonstrate that all patient-contacting components of the device system hardware are biocompatible.

- (6) Software verification, validation and hazard analysis must be performed.
- (7) Device technological characteristics must incorporate design features to limit the number of scans and duration of device system use by the lay user to mitigate unnecessary ultrasound exposure.
- (8) A training program must be included with sufficient educational elements so that upon completion of the training program, the user can operate the device system in the intended use environment.
- (9) Human factors assessment must demonstrate the following:
 - (i) The user can correctly use the device system in the intended use environment with the provided instructions and training materials; and
 - (ii) The user understands situations in which the device system should not be used.
- (10) Labeling must be included for the patient and healthcare professional that includes the following:
 - (i) A summary of clinical performance testing written for the intended reader;
 - (ii) For software labeling, hardware compatibility information;
 - (iii) The following statements:
 - (A) A statement that the images and data acquired using the software are to be interpreted by qualified healthcare professionals;
 - (B) A statement that the device system should not be used to replace or delay in-office/in-clinic assessment when needed;
 - (C) A statement that users of the device system must complete the device-specific user training program prior to performing their first scan; and
 - (D) A statement on adherence to the As Low As Reasonably Achievable (ALARA) principle and the device controls available to minimize ultrasound bioeffects.
 - (iv) For healthcare professional labeling, instructions for configuring the limits on device system use; and
 - (v) For patient labeling:
 - (A) Hardware platform requirements;
 - (B) A warning that the device system is not intended to be used outside of what has been prescribed, and to be aware of limits placed upon device system use by their healthcare professional;
 - (C) Instructions for reprocessing of any reusable components; and
 - (D) Instructions for proper handling of the device hardware when it is no longer needed, including disposal methods, and/or return requirements.

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 ultrasound imaging system for acquiring images at home by lay users 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 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).

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 Paramita Sengupta at 240-402-7682.

Sincerely,

for Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health