August 19, 2026

Vitestro
% Michael Daniel
President
Daniel & Daniel Consulting
P.O. Box 129
Minden, Nevada 89423

Re: DEN250046
Trade/Device Name: Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US)
Regulation Number: 21 CFR 880.6975
Regulation Name: Robotic peripheral venous blood collection system
Regulatory Class: Class II
Product Code: SIW
Dated: June 5, 2026
Received: June 5, 2026

Dear Michael Daniel:

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 Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Aletta® ARPD™ is intended to perform autonomous, ultrasound-guided, venipuncture and collection of blood for diagnostic purposes in adult outpatients, monitored by a trained phlebotomist. One phlebotomist may supervise up to three Aletta® ARPD™ devices simultaneously.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US), and substantially equivalent devices of this generic type, into Class II under the generic name robotic peripheral venous blood collection system.

FDA identifies this generic type of device as:

> **Robotic peripheral venous blood collection system**. A robotic peripheral venous blood collection system is an electromechanical device used to obtain blood samples from peripheral veins for diagnostic purposes. The device uses robotic systems to assist with the blood collection procedure,

including vessel identification, targeting, and/or needle insertion, and may perform its functions in an automated or autonomous manner.

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 September 26, 2025, FDA received your De Novo requesting classification of the Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US) 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 FDA has determined that, for the previously stated indications for use, the Aletta® Autonomous Robotic Phlebotomy Device (ARPD™) (Gen1 US) 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 mechanical failure or malfunction (including unanticipated device movement and failure of passive safety mechanisms) resulting in: • Blunt force injury • Unintended puncture • Hematoma • Entrapment • Prolonged procedure time	Clinical performance testing Non-clinical performance testing Software verification, validation and hazard analysis
Device blood collection failure, leading to unnecessary tissue injury and/or referral to manual phlebotomy, due to: • Failure to identify a suitable vein • Failed or repeat puncture • Incompatible sample collection device	Clinical performance testing Non-clinical performance testing Human factors/usability testing Labeling
Insufficient sample quantity and/or quality, leading to inaccurate test results, or the need for a repeat blood collection	Clinical performance testing Non-clinical performance testing Human factors/usability testing

Risks to Health	Mitigation Measures
	Labeling
Infection, including infection due to cross-contamination and bloodborne pathogen exposure	Human factors/usability testing Sterilization validation Reprocessing validation Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction	Biocompatibility evaluation
Electromagnetic interference or electrical fault resulting in device failure, tissue injury, or electric shock	Electrical safety testing Electromagnetic compatibility testing

In combination with the general controls of the FD&C Act, the robotic peripheral venous blood collection system is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended in the intended patient population under anticipated conditions of use. This testing must include:
  (i) First puncture success rates;
  (ii) Characterization of collected sample quality and quantity, based on requirements for compatible sample collection devices and intended downstream applications;
  (iii) Rates of adverse events, including severity, causes, and outcomes; and
  (iv) Sub-group analyses based on patient characteristics affecting device performance or safety (e.g., skin tone, body mass index, anticoagulation, or known difficult intravenous access).

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:
  (i) Device motion accuracy and precision;
  (ii) Verification of design characteristics intended to mitigate needle reuse;
  (iii) Verification of maximum autonomous motion speed and force under all conditions of use;
  (iv) Validation of safe system behavior upon fault or failure;
  (v) Verification of the specified useful life under estimated worst-case use conditions.

(3) Human factors/usability testing must demonstrate that all intended users can correctly use the device based on the directions for use, including training materials when applicable, in all intended use environments.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(6) Performance data must demonstrate the sterility of all blood path contacting device components.

(7) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(8) Performance data must validate the reprocessing instructions for the reusable components of the device.

(9) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(10) Labeling must include:

(i) A summary of the clinical performance testing with the device, including:
  (A) The patient population and intended use environment(s) studied;
  (B) First puncture success rate;
  (C) The expected rate of referral to manual phlebotomy;
  (D) Device- and procedure-related adverse events; and
  (E) Subgroups with deviations in device effectiveness or safety.
(ii) Training needed for the safe use of the device;
(iii) Compatible blood collection devices;
(iv) Validated methods and instructions for reprocessing of any reusable components;
(v) The useful life of the device;
(vi) Disposal instructions for consumable components.

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 robotic peripheral venous blood collection system 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 Michael Lancina at 301-796-1459.

Sincerely,

JULIANE C. LESSARD -S

Juliane C. Lessard, Ph.D.
Director
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