October 24, 2018

Ansh Labs LLC
Ajay Kumar
Director of Operations
445 Medical Center Blvd.
Webster, Texas 77598

Re: DEN180004
Trade/Device Name: picoAMH ELISA
Regulation Number: 21 CFR 862.1093
Regulation Name: Menopause test system
Regulatory Class: Class II
Product Code: QDH
Dated: January 19, 2018
Received: January 22, 2018

Dear Ajay Kumar:

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 picoAMH ELISA, a prescription device with the following indications for use:

> The picoAMH ELISA is an enzyme-linked immunosorbent assay (ELISA) for the in vitro quantitative measurement of anti-Müllerian hormone (AMH), also known as Müllerian Inhibiting Substance (MIS), concentrations in human serum. It is intended to be used as an aid in the determination of menopausal status in women between 42 and 62 years of age. This assay should only be used in conjunction with other clinical and laboratory findings and results from this test alone should not be used to make diagnostic or treatment decisions. It is intended for in vitro diagnostic use and for prescription use only.

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. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the picoAMH ELISA, and substantially equivalent devices of this generic type, into Class II under the generic name Menopause test system.

FDA identifies this generic type of device as:

> **Menopause test system**. A menopause test system is an in vitro diagnostic device intended to measure hormones or other analytes in human clinical specimens as an aid in the determination of menopausal status in women.

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 22, 2018, FDA received your De Novo requesting classification of the picoAMH ELISA. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the picoAMH ELISA 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 picoAMH ELISA 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	**Identified Mitigations**
Incorrect test results	General controls and special controls (1) and (2)
Incorrect interpretation of test results	General controls and special controls (1) and (2)

In combination with the general controls of the FD&C Act, the menopause test system is subject to the following special controls:

(1) Design verification and validation must include the following:

(i) An appropriate traceability plan to minimize the risk of drift in the menopause test system results over time.

(ii) Detailed documentation of a clinical study to demonstrate clinical performance or, if appropriate, results from an equivalent sample set. This detailed documentation must include the following information:

(A) Results must demonstrate appropriate clinical performance relative to a well-accepted and appropriate comparator.

(B) Data must demonstrate accuracy of device output for each indicated specimen type throughout the device measuring range as appropriate for the intended use population.

(2) The 21 CFR 809.10 labeling must include the following:

(i) A statement in the intended use that the device is intended to be used for the determination of menopausal status only in conjunction with other clinical and laboratory findings prior to any diagnostic or treatment decisions.

(ii) A limiting statement that the device is intended to be used for the determination of menopausal status only in conjunction with other clinical and laboratory findings prior to any diagnostic or treatment decisions.

(iii) A limiting statement appropriately describing the risks of false test results and that test results should not be relied upon in clinical decision making (e.g., to discontinue contraceptive use and/or to evaluate patients for the presence of endometrial cancer) without other clinical and laboratory findings.

In addition, this is a prescription device.

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 Menopause test 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 Parts 801 and 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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/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 Juliane Lessard at 240-402-6126.

Sincerely,

Courtney H. Lias -S

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Director
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