April 20, 2018

Lin-Zhi International, Inc.
Bernice Lin
Vice President
2945 Oakmead Village Court
Santa Clara, California 95051

Re: DEN170010
Trade/Device Name: LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay
Regulation Number: 21 CFR 862.3590
Regulation Name: Meprobamate test system
Regulatory Class: Class II
Product Code: QBK
Dated: February 10, 2017
Received: February 21, 2017

Dear Bernice Lin:

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 LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay, a prescription device with the following indications for use:

> The LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of carisoprodol metabolite (meprobamate) in human urine at a cutoff value of 100 ng/mL when calibrated against meprobamate. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.
>
> The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for verification by a confirmatory method such as GC/MS, LC/MS or permitting laboratories to establish quality control procedures.
>
> The assay provides only a preliminary analytical result. A more specific alternative chemical confirmatory method (e.g., gas or liquid chromatography and mass spectrometry) must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment must be exercised with any drug of abuse test, particularly when the preliminary test result is positive.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay, and substantially equivalent devices of this generic type, into Class II under the generic name meprobamate test system.

FDA identifies this generic type of device as:

> **Meprobamate test system**. A meprobamate test system is a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (e.g., prodrugs).

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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 classifying the device type.

On February 21, 2017, FDA received your De Novo requesting classification of the LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay 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 LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay 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	**Required Mitigations**
Clinical action based on incorrect test results (false positive results, false negative results) may lead to inappropriate clinical decision making	Special controls (1), (2), and (3)
Incorrect understanding of the device and test system and results may lead to inappropriate clinical decision making	Special controls (2) and (3)

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

1) Design verification and validation must include:

   (i) Robust data demonstrating the accuracy of the device when used in the intended specimen matrix. The accuracy data must include a comparison between the meprobamate test system results and meprobamate results that are measured on an FDA-accepted measurement method that is specific and accurate (e.g., gas or liquid chromatography combined with tandem mass spectrometry).

   (ii) Robust analytical data demonstrating the performance characteristics of the device, including, but not limited to, specificity, cross-reactivity to relevant endogenous and exogenous substances, and the reproducibility of analyte detection around the cutoff(s).

2) The intended use of the device must not include an indication for use in monitoring therapeutic drug concentrations or informing dosing adjustment decisions.

3) Your 21 CFR 809.10 labeling must include the following:

   (i) If indicated for use as a screening test to identify preliminary results for further confirmation, the intended use must state "This assay provides only a preliminary analytical result. A more specific alternative chemical confirmatory method (e.g., gas or liquid chromatography and mass spectrometry) must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment must be exercised with any drug of abuse test, particularly when the preliminary test result is positive."

   (ii) A limiting statement that reads as follows: "This test should not be used to monitor therapeutic drug concentrations or to inform dosing adjustment decisions."

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 meprobamate 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 Part 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 Alain Silk at 301-796-2129.

Sincerely,

Courtney H. Lias -S

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