



April 16, 2020

Saladax Biomedical Inc
Sue Werner
Senior Director of Regulatory and Quality
116 Research Drive
Bethlehem, PA 18015

Re: DEN190028

Trade/Device Name: MyCare Psychiatry Clozapine Assay Kit
Regulation Number: 21 CFR 862.3245
Regulation Name: Clozapine test system
Regulatory Class: Class II
Product Code: QKT
Dated: May 23, 2019
Received: May 24, 2019

Dear Sue Werner:

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 MyCare Psychiatry Clozapine Assay Kit, a prescription device with the following indications for use:

The MyCare Psychiatry Clozapine Assay Kit is intended for the in vitro quantitative measurement of clozapine in adult human serum using automated clinical chemistry analyzers. Measurements obtained can be used to aid in the management of individuals prescribed clozapine for treatment-resistant schizophrenia. This assay should be used in conjunction with other clinical and laboratory findings and results from this test alone should not be used to make treatment decisions.

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 MyCare Psychiatry Clozapine Assay Kit, and substantially equivalent devices of this generic type, into Class II under the generic name Clozapine test system.

FDA identifies this generic type of device as:

Clozapine test system. A clozapine test system is a device intended to measure clozapine in human specimens. Measurements obtained by this device are used in monitoring levels of clozapine to ensure appropriate therapy in patients with treatment-resistant schizophrenia.

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 May 24, 2019, FDA received your De Novo requesting classification of the MyCare Psychiatry Clozapine Assay Kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MyCare Psychiatry Clozapine Assay Kit 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 MyCare Psychiatry Clozapine Assay Kit 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Incorrect test results	Certain design verification and validation activities Certain labeling information
Incorrect interpretation of test results	Certain design verification and validation activities Certain labeling information

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

- (1) Design verification and validation must include the following:
 - (i) Precision study data that demonstrates precision that is clinically appropriate, as determined by FDA, for the clozapine test system. Precision studies must include a minimum of three samples containing different concentrations of clozapine including near medical decision points and throughout the expected therapeutic range of clozapine. Samples near the medical decision points must be clinical specimens collected from patients taking clozapine;
 - (ii) Method comparison data that demonstrates accuracy that is clinically acceptable, as determined by FDA, for the clozapine test system;
 - (iii) Data from studies that demonstrate that the device is free from clinically significant interference, as determined by FDA, from commonly co-administered medications that are used in patients with treatment-resistant schizophrenia; and

- (iv) Data from studies that demonstrate that the device is free from clinically significant cross-reactivity, as determined by FDA, from major circulating metabolites found in the intended use population.
- (2) The labeling required under 21 CFR 809.10 must include a limiting statement conveying that the assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures and that results from the assay alone should not be used in making treatment 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 clozapine 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/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.

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 Eveline Arnold at 240-402-5334.

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
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