DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 16, 2017

Elizabeth Hamelin, M.S.
Chemist
Centers for Disease Control and Prevention
Division of Laboratory Sciences/National Center for Environmental Health
4770 Buford Highway NE
Atlanta, GA 30341

Re: k122282 – Order Granting the Request for De Novo Classification
Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 862.3652
Regulation Name: Organophosphate Test System
Regulatory Classification: Class II (special controls)
Product Code: PDY
Dated: May 29, 2013
Received: May 31, 2013

Dear Ms. Hamelin:

This letter corrects our letter sent August 8, 2013 and dated August 8, 2013.

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 Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS, a prescription device under 21 CFR Part 801.109, that is indicated for the quantitation of specific organophosphate metabolites by LC/MS/MS. The device system includes organophosphate metabolite calibrators to calibrate the system and organophosphate metabolite controls for quality control monitoring of the system. This device is intended for use in a single laboratory to detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device will be used following an exposure or suspected exposure event to confirm exposure, identify the causative agent, and distinguish exposed from the unexposed patients. FDA concludes that this device, and substantially equivalent devices, should be classified into class II.

FDA identifies this generic type of device as: Organophosphate test system

An organophosphate test system is a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the confirmation and investigation of organophosphate exposure.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a type of device that has not been previously classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(l), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall by order classify the device, which shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) and 513(i) of the FD&C Act, FDA issued an order on May 2, 2013, finding the Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS not substantially equivalent to any device within a type that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or that was subsequently reclassified into class I or class II, which means this device is automatically in class III under section 513(f)(1). On May 31, 2013, FDA received your *de novo* requesting classification of the Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS 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 the Quantitation of Organophosphate Metabolites in Human Urine by LC/MS/MS indicated for:

> This device is intended for the quantitation of specific organophosphate metabolites by LC/MS/MS. The device system includes organophosphate metabolite calibrators to calibrate the system and organophosphate metabolite controls for quality control monitoring of the system. This device is intended for use in a single laboratory to detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device will be used following an exposure or suspected exposure event to confirm exposure, identify the causative agent, and distinguish exposed from the unexposed patients.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II (special) controls identified later in this order, along with applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Potential Risks and Required Mitigation Measures

Identified Potential Risk	**Required Mitigation Measure**
False Positive	1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. 2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and

Identified Potential Risk	Required Mitigation Measure
	accuracy across the measuring range and near medical decision points.
False Negative	1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. 2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.
Public Health Risk from Incorrect Test Results	1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. 2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

In addition to the general controls of the FD&C Act, the organophosphate test system is subject to the following special controls:

1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response.
2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

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 organophosphate test system they intend to market and receive clearance to market from FDA prior to marketing the device.

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 market your device, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Holly Brevig at 301-402-2817

Sincerely yours,

Courtney H. Lias -S

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