



Food and Drug Administration
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ARK DIAGNOSTICS, INC
KENNETH C. KASPER, Ph.D., RAC
EXECUTIVE DIRECTOR, QUALITY AND REGULATORY AFFAIRS
48089 FREMONT BLVD
FREMONT, CA 94538

Re: DEN160033
ARK Voriconazole II Assay Test System
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 862.3970
Regulation Name: Voriconazole test system
Regulatory Classification: Class II
Product Code: PUJ
Dated: July 14, 2016
Received: July 15, 2016

Dear Dr. Kasper:

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 ARK Voriconazole II Assay Test System. The ARK Voriconazole II Assay Test System is a prescription device that is indicated for use as follows:

ARK Voriconazole II Assay Test System includes separately provided test kits for the ARK Voriconazole II Assay, ARK Voriconazole II Calibrator, and ARK Voriconazole II Control.

The ARK Voriconazole II Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of voriconazole in human serum on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of voriconazole to help ensure appropriate therapy. The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

ARK Voriconazole II Calibrator is intended for use in calibration of the ARK Voriconazole II Assay.

ARK Voriconazole II Control is an assayed quality control material intended for use in quality control of the ARK Voriconazole II Assay.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the ARK Voriconazole II Assay Test System,

and substantially equivalent devices of this generic type, into class II under the generic name, “Voriconazole test system”.

FDA identifies this generic type of device as: **Voriconazole test system.**

A voriconazole test system is a device intended to measure voriconazole in human serum. Measurements obtained by this device are used in monitoring levels of voriconazole to ensure appropriate therapy.

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 July 15, 2016, FDA received your *de novo* requesting classification of the ARK Voriconazole II Assay Test System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ARK Voriconazole II Assay Test System 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 ARK Voriconazole II Assay Test System indicated for use as follows:

ARK Voriconazole II Assay Test System includes separately provided test kits for the ARK Voriconazole II Assay, ARK Voriconazole II Calibrator, and ARK Voriconazole II Control.

The ARK Voriconazole II Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of voriconazole in human serum on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of voriconazole to help ensure appropriate therapy. The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

ARK Voriconazole II Calibrator is intended for use in calibration of the ARK Voriconazole II Assay.

ARK Voriconazole II Control is an assayed quality control material intended for use in quality control of the ARK Voriconazole II Assay.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that class II special controls identified later in this order, along with the applicable general controls, including the design controls under 21 CFR part 820, 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 Table 1.

Table 1 – Identified Risks to Health and Identified Mitigations

Identified Risks to Health	Identified Mitigations
Clinical action (e.g., dose adjustments) based on falsely elevated inaccurate voriconazole results may lead to decreased clinical efficacy of the drug and consequently poorer clinical outcomes.	General controls and special controls (1), and (2)
Clinical action (e.g. dose adjustments) based on falsely low inaccurate voriconazole results may lead to an increased risk of toxicity.	General controls and special controls (1), and (2)

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

- 1) Premarket notification submissions must include the following information:
 - A. Data demonstrating the precision of the voriconazole test system. Precision studies must include a minimum of three samples containing different concentrations of voriconazole, including near medical decision points at the high and low end of the expected therapeutic range. Samples with concentrations near medical decision points must be individual or pooled clinical specimens, collected from patients taking voriconazole.
 - B. Method comparison data demonstrating accuracy of the voriconazole test system. Method comparison data must be collected at three laboratory sites. The comparator method must not be subject to bias due to non-specific detection of voriconazole.
 - C. Data from interference studies performed to evaluate potential interference from co-administered medications used for conditions in which voriconazole is indicated.
 - D. Data from studies performed to evaluate cross reactivity of the major metabolite, N-oxide voriconazole.

- 2) Your 809.10(b)(5)(ii) compliant labeling must include a warning statement as follows: “This assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.”

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 Voriconazole test system they intend to market and receive clearance to market from FDA 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); 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.

If you have any questions concerning this classification order, please contact Lili Duan at 301-796-7404.

Sincerely,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Devices
Office of In Vitro Diagnostics
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