DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 18, 2017

ID-FISH Technology, Inc.
Jyotsna Shah
Official Correspondent
797 San Antonio Road
Palo Alto, California 94303

Re: DEN160025
Trade/Device Name: ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit
Regulation Number: 21 CFR 866.3367
Regulation Name: Device to detect and identify microbial nucleic acids by FISH in clinical specimens
Regulatory Class: Class II
Product Code: PYN
Dated: June 19, 2017
Received: June 20, 2017

Dear Jyotsna Shah:

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 ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit, a prescription device, with the following indications for use:

> ID-FISH Plasmodium Genus Test Kit (PlasG) and ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit (PlasFV) are intended for in vitro diagnostic use in the clinical laboratory for detection of Plasmodium species in human venous whole blood (EDTA) samples from patients suspected of Plasmodium infection. The test kits are intended to aid in the diagnosis of malaria and to aid in the differential diagnosis of P. falciparum and P. vivax infection. The test kits should be used only on samples from patients with a clinical history, signs and symptoms consistent with malaria, and are not intended as a screen for asymptomatic patients.
>
> The ID-FISH Plasmodium Genus Test Kit is a qualitative test for detection of malaria parasites in blood smears. Positive results should be supplemented with the Plasmodium species specific test kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit for identification and differentiation of Plasmodium falciparum and Plasmodium vivax. The results of these test kits should be used in conjunction with other diagnostic test

results. Clinical performance has not been established for P. ovale, P. malariae, or P. knowlesi.

For in vitro diagnostic use only
For prescription use only
For professional use only

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit, and substantially equivalent devices of this generic type, into Class II under the generic name "Device to detect and identify microbial nucleic acids by FISH in clinical specimens."

FDA identifies this generic type of device as: **Device to detect and identify microbial nucleic acids by FISH in clinical specimens**.

A device to detect and identify microbial nucleic acids by fluorescence in situ hybridization (FISH) in clinical specimens is an in vitro diagnostic device intended for the detection and identification of microbial pathogens in specimens collected from patients with signs and symptoms of infection. The device is intended to aid in the diagnosis of human disease in conjunction with clinical signs and symptoms and other laboratory findings.

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 June 20, 2017, FDA received your *de novo* requesting classification of the ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test 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 the ID-FISH Plasmodium Genus Test Kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit indicated as follows:

ID-FISH Plasmodium Genus Test Kit (PlasG) and ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit (PlasFV) are intended for in vitro diagnostic use in the clinical laboratory for detection of Plasmodium species in human venous whole blood (EDTA) samples from patients suspected of Plasmodium infection. The test kits are intended to aid in the diagnosis of malaria and to aid in the differential diagnosis of P. falciparum and P. vivax infection. The test kits should be used only on samples from patients with a clinical history, signs and symptoms consistent with malaria, and are not intended as a screen for asymptomatic patients.

The ID-FISH Plasmodium Genus Test Kit is a qualitative test for detection of malaria parasites in blood smears. Positive results should be supplemented with the Plasmodium species specific test kit, ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit for identification and differentiation of Plasmodium falciparum and Plasmodium vivax. The results of these test kits should be used in conjunction with other diagnostic test results. Clinical performance has not been established for P. ovale, P. malariae, or P. knowlesi.

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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 general 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 identification or lack of identification of a pathogenic microorganism by the device can lead to improper patient management	General Controls and Special Controls (1), (2), (3), (4), (5), (6), and (7)
Failure to correctly interpret test results	General Controls and Special Controls (5), (6), and (7)
Failure to correctly operate the instrument	General Controls and Special Controls (5) and (6)

In combination with the general controls of the FD&C Act, a device to detect and identify microbial nucleic acids by FISH in clinical specimens is subject to the following special controls:

1) Premarket notification submissions must include detailed device description documentation, including the device components, instrument requirements, ancillary reagents required but not provided, and a detailed explanation of the methodology including all pre-analytical methods for processing of specimens, probe sequences, and rationale for probe sequence selection.

2) Premarket notification submissions must include a detailed description of the fluorophores, signal source, detection mechanism and method of result interpretation.
3) Premarket notification submissions must include detailed documentation from the following analytical studies: analytical sensitivity (Limit of Detection), inclusivity, reproducibility, interference, cross reactivity, and specimen stability.
4) Premarket notification submissions must include detailed documentation from a clinical study that includes prospective (sequential) samples. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from appropriate and well-accepted comparator methods.
5) The 21 CFR 809.10(b)(2) compliant labeling must include a statement that the device is intended to be used in conjunction with clinical history, signs, symptoms, and the results of other diagnostic testing.
6) The 21 CFR 809.10(b)(9) compliant labeling must include a detailed explanation of the interpretation of results and acceptance criteria for any quality control testing.
7) The 21 CFR 809.10(b)(5)(ii) compliant labeling must include a limitation that negative results do not preclude the possibility of infection.

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on a device to detect and identify microbial nucleic acids by FISH in clinical specimens 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 Part 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 the contents of the letter, please contact Noel Gerald at 301-796-4695 or please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100, or at its internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health