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

September 22, 2014

T2 Biosystems, Inc.
C/O Sarah Kalil
Chief Operating Officer
101 Hartwell Avenue
Lexington, MA 02421

Re: DEN140019
T2Candida Panel and T2Dx® Instrument
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 866.3960
Regulation Name: Nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens
Regulatory Classification: Class II
Product Code: PII, NSU
Dated: May 27, 2014
Received: May 27, 2014

Dear Ms. Kalil:

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 T2Candida Panel and T2Dx® Instrument, a prescription device. The intended use of the T2Candida Panel and T2Dx® Instrument is

> The T2Candida Panel and T2Dx® Instrument is a qualitative T2 Magnetic Resonance (T2MR®) assay for the direct detection of *Candida* species in EDTA human whole blood specimens from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. The T2Candida Panel identifies five species of *Candida* and categorizes them into the following three species groups:
>
> 1. *Candida albicans* and/or *Candida tropicalis*,
> 2. *Candida parapsilosis*
> 3. *Candida glabrata* and/or *Candida krusei*
>
> The T2Candida Panel does not distinguish between *C. albicans* and *C. tropicalis*. The T2Candida Panel does not distinguish between *C. glabrata* and *C. krusei*.

> The T2Candida Panel is indicated for the presumptive diagnosis of candidemia. The T2Candida Panel is performed independent of blood culture. Concomitant blood cultures are necessary to recover organisms for susceptibility testing or further identification.
>
> The T2Candida positive and negative External Controls are intended to be used as quality control samples with the T2Candida Panel when run on the T2Dx® instrument system. These controls are not intended for use with other assays or systems.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the T2Candida Panel and T2Dx® Instrument, and substantially equivalent devices of this generic type, into class II under the generic name, "Nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens."

FDA identifies this generic type of device as: Nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens.

A nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens is a qualitative in vitro device intended for the amplification, detection, and identification of microbial-associated nucleic acid sequences from patients with suspected bloodstream infections. This device is intended to aid in the diagnosis of bloodstream infection when used in conjunction with clinical signs and symptoms and other laboratory findings.

Section 513(f)(2) of the Food, Drug & Cosmetic Act (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 FD&C 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 FD&C 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 FD&C 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 May 27, 2014, FDA received your *de novo* request for classification of the T2Candida Panel and T2Dx® Instrument. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the T2Candida Panel and T2Dx® Instrument 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 T2Candida Panel and T2Dx® Instrument intended for use as follows

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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 the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Risks and Required Mitigations

Identified Risks	**Required Mitigations**
Incorrect identification of a pathogenic microorganism by the device can lead to improper patient management	Special Controls (1), (2), (3), (4), (5)
Failure to correctly interpret test results	Special Control (6)
Failure to correctly operate the instrument	Special Controls (7) and (8)

In combination with the general controls of the FD&C Act, the nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens is subject to the following special controls:

1) Premarket notification submissions must include detailed device description documentation, including the device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including primer/probe sequence, design, and rationale for sequence selection.
2) Premarket notification submissions must include detailed documentation from the following analytical and clinical performance studies: Analytical sensitivity (Limit of Detection), reactivity, inclusivity, precision, reproducibility, interference, cross reactivity, carry-over, and cross contamination.
3) Premarket notification submissions must include detailed documentation from a clinical study. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from well-accepted reference methods.
4) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.
5) The device labeling must include limitations regarding the need for culture confirmation of negative specimens, as appropriate.
6) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.
7) Premarket notification submissions must include details on an end user device training program that will be offered while marketing the device, as appropriate.
8) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

In addition, this is a prescription device. 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 nucleic acid-based device for the amplification, detection and identification of microbial pathogens directly from whole blood specimens they intend to market prior to marketing the device and receive clearance to market from FDA.

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.

If you have any questions concerning this classification order, please contact Patricia Conville at 301-796-6942.

Sincerely yours,

Sally A. Hojvat -S

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