December 12, 2017

T2 Biosystems, Inc.
Anne Whalen
Sr. Director, Regulatory and Clinical Affairs
101 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K173536
Trade/Device Name: T2Candida 1.1 Panel
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 Class: Class II
Product Code: PII
Dated: November 13, 2017
Received: November 15, 2017

Dear Anne Whalen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
T2Candida 1.1 Panel

Indications for Use *(Describe)*

T2Candida 1.1 Panel and T2Dx Instrument is a qualitative T2 Magnetic Resonance (T2MR) assay for the direct detection of Candida species in K2EDTA human whole blood specimens from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. The T2Candida 1.1 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 1.1 Panel is indicated for the presumptive diagnosis of candidemia. The T2Candida 1.1 Panel is performed independent of blood culture. Concomitant blood cultures are necessary to recover organisms for susceptibility testing or further identification. The T2Candida QCheck Positive and T2Dx QCheck Negative External Controls are intended to be used as quality control samples with the T2Candida 1.1 Panel when run on the T2Dx Instrument. These controls are not intended for use with other assays or systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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15. 510(k) SUMMARY

Date of Summary November 13, 2017

Product Name T2Candida® 1.1 Panel

Sponsor

T2 Biosystems, Inc.
101 Hartwell Avenue
Lexington, MA 02421

Correspondent

T2Biosystems, Inc.
Anne Marie Whalen, PhD
Sr. Director, Regulatory and Clinical Affairs
Office: (781) 761-4647
Mobile: (908) 581-3440
Fax : (781) 357-3080
awhalen@t2biosystems.com

Device Trade or Proprietary Name T2Candida® 1.1 Panel

Regulation 21 CFR 866.3690

Common Name Candida Species Nucleic Acid Detection System

Product Code PII

Classification Class II

Classification Panel Microbiology (83)

Intended Use Statement

The **T2Candida 1.1** Panel run on the 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 groups:

1. *Candida albicans* and/or *Candida tropicalis*,
2. *Candida parapsilosis*
3. *Candida glabrata* and/or *Candida krusei*

The **T2Candida 1.1** Panel does not distinguish between *C. albicans* and C. *tropicalis*. The **T2Candida 1.1** 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 (**T2Candida QCheck**) and negative External Controls (**T2Dx QCheck**) are intended to be used as quality control samples with the **T2Candida 1.1** Panel when run on the T2Dx Instrument. These controls are not intended for use with other assays or systems.

Limitations:

For prescription use only. Please refer to the T2Bacteria Panel labeling for a more complete list of warnings, precautions, and contraindications.

Principles of Operation:

The fundamental scientific technology and principle of operation of the **T2Candida 1.1 Panel** on the T2Dx instrument is equivalent to that used in the original T2Candida Panel, as submitted and cleared (DEN140019, Summary Decision September, 2014). The T2Candida 1.1 Panel utilizes the same magnetic resonance-based detection (T2®MR technology) to qualitatively detect the same five species of Candida: *Candida albicans and/or Candida tropicalis, Candida parapsilosis, Candida glabrata and/or Candida krusei*, direct from K_2EDTA-treated human whole blood. The T2Candida 1.1 Panel, run on the T2Dx instrument, performs sample concentration and Candida target DNA amplification for direct detection of species-specific amplicon at a limit of detection as low as 1 CFU/mL in approximately 3.5 hours. The test incorporates an Internal Control (IC) for monitoring test performance. The internal control for the T2Candida 1.1 Panel has not been changed from the original assay. The workflow for T2Candida 1.1 Panel is the same as the original cleared test and can only be performed on the T2Dx instrument, a bench-top, automated sample-to-result system, which performs all steps in the test after specimen loading.

In response to stability issues caused by the generation of inhibitory byproducts originating from two, foil-sealed tubes containing calcium hypochlorite ("bleach tubes") in the T2Candida Cartridge, a design change to remove the bleach tubes from the cartridge configuration and modify the software to remove the bleach transfer steps from the T2Dx workflow (collectively referred to the "the bleach steps") was made under design control. The bleach tubes were originally included as a precautionary element of post-testing decontamination, and are unrelated to the performance of the assay, and do not impact the fundamental scientific technology of the T2Candida Panel.

With the exception of the addition of an assay version to the T2Candida label (1.1), and the addition of a brand name for positive (**T2Candida QCheck**) and negative (**T2Dx QCheck**) External Controls, the intended use and fundamental scientific technology of these product remains unchanged. There are no changes except branding to the external controls.

Performance Data

The removal of the bleach steps does not impact the fundamental scientific technology associated with the T2Candida Panel intended use or operation. Two performance issues were addressed to validate the T2Candida 1.1 Panel, run in the absence of the bleach steps: the potential of higher cross-contamination in the absence of the bleach steps and recovery of stability in the absence of the bleach by-product inhibitor.

1. To determine that the absence of bleach does not result in higher levels of cross-contamination/carryover (i.e. lower specificity) two specificity studies were conducted with human whole blood pooled from healthy donors triple-spiked with either high titer (100 CFU or 1000 CFU) of *C. albicans, C. parapsilosis and C. glabrata* (APG) or *C. tropicalis and C. parapsilosis and C. krusei* (TPK). Negative samples were human whole blood samples from the same pool without spiking. Samples were loaded such that Negative Samples and Positive APG or TPK were positioned in adjacent drawers. Results obtained with the T2Candida 1.1 Panel (with bleach tubes removed) were compared with original data submitted to FDA (DEN140019).

Channel	**T2Candida Panel (DEN140019 Predicate) %Specificity (± 95% CI)**	**T2Candida 1.1 Panel %Specificity (± 95% CI)**
A/T	99.5 (97.4-99.9)	100.0 (97.1-100.0)
P	100.0 (98.3-100.0)	99.2 (95.7-99.9)
K/G	99.5 (97.4-99.9)	99.2 (95.7-99.9)
Overall	99.7 (98.9-99.9)	99.5 (98.1-99.9)

   The results verified that specificity for each target was statistically equivalent to the original claim.

2. Stability studies of the T2Candida 1.1 Cartridge demonstrated that the reduced stability originally observed in the presence of the bleach steps has been mitigated. Based on these studies, expiration dates can be set at 8 months, with studies ongoing to extend this product shelf-life.

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Time point	**Negative Sample Equivalence Test**			**Positive Sample Equivalence Test**		
Cartridge Stability Lot	**Lot 1 WO-05642**	**Lot 2 WO-05822**	**Lot 3 WO-05920**	**Lot 1 WO-05642**	**Lot 2 WO-05822**	**Lot 3 WO-05920**
Three Months (T3)	Pass	Pass	Pass	Pass	Pass	Pass
Six Months (T6)	Pass	Pass	Pass	Pass	Pass	Pass
Nine Months (T9)	Pass	Pass	Pass	Pass	Pass	Pass

Elimination of the bleach steps required software revisions. This set of commands, which executed the bleach transfer from the bleach tubes to all spent reaction vessels in the cartridge assembly, were eliminated for T2Candida 1.1 Panel. The Assay Definition File and T2Dx instructions are the same in all other ways, including the task scheduler, timing of each task and safe-waiting limits. The removed software commands do not interact with other steps in the workflow and are executed after results are reported; therefore, results reporting are not affected.

Conclusion

The design change was implemented to address the issue of product stability by removal of two bleach tubes from the T2Candida 1.1 Cartridge and elimination of the bleach transfer steps. Removal of the bleach steps has allowed for an acceptable shelf-life for the T2Candida 1.1 Panel, can be implemented with no discernible impact on assay performance, with demonstrated equivalence to key validation criteria, and without changing the intended use or fundamental scientific technology of the original cleared test. Validation of the design change demonstrates equivalent performance to the original test, but with increased stability.

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