September 13, 2024

T2Biosystems, Inc.
Rachel Gilbert
Manager, Regulatory Affairs
101 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K234063
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, NSU
Dated: August 15, 2024
Received: August 15, 2024

Dear Rachel Gilbert:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234063

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 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 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 positive and negative External Controls (T2Candida QCheck Positive Kit and the T2Dx QCheck Negative Kit) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date of Summary	September 13, 2024
Product Name	T2Candida® 1.1 Panel
Sponsor	T2Biosystems, Inc. 101 Hartwell Avenue Lexington, MA 02421
Correspondent	Rachel Gilbert Associate Director, Regulatory Affairs 781-226-2767, 1970 rgilbert@t2biosystems.com
Device Trade or Proprietary Name	T2Candida® 1.1 Panel
Regulation	21 CFR 866.3960
Common Name	Candida Species Nucleic Acid Detection System
Product Code	PII, NSU
Classification	Class II

The purpose of this pre-market 510(k) submission is to amend the T2Candida 1.1 Panel cleared under K173536 to amend labeling regarding testing in pediatric patients.

No significant changes have been made to the device components or technology since the clearance of the T2Candida 1.1 Panel.

Intended Use

T2Candida® 1.1 Panel and T2Dx® Instrument is a qualitative T2 Magnetic Resonance (T2MR®) assay for the direct detection of *Candida* species in K_2EDTA 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 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 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 positive and negative External Controls (T2Candida QCheck Positive Kit and the T2Dx QCheck Negative Kit) 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 T2Candida 1.1 Panel labeling for a more complete list of warnings, precautions, and contraindications.

Methodology

The T2Candida 1.1 Panel utilizes magnetic resonance-based detection (T2®MR technology) to qualitatively detect five species of Candida: *Candida albicans* and/or *Candida tropicalis*, *Candida parapsilosis*, *Candida glabrata* and/or *Candida krusei*, direct from K2EDTA-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.

Device Description

The T2Candida 1.1 Panel and T2Dx Instrument is comprised of the T2Candida 1.1 Panel performed on the T2Dx Instrument. The T2Candida 1.1 Panel is a qualitative molecular diagnostic assay that employs a whole blood compatible PCR amplification followed by T2 magnetic resonance (T2MR) detection. The T2Candida 1.1 Panel is performed on the T2Dx Instrument which executes all steps after specimen loading. A K_2EDTA whole blood specimen is loaded onto the T2Candida 1.1 Sample Inlet, which is then placed on the T2Candida 1.1 Cartridge along with the T2Candida 1.1 Reagent Tray. The Reagent Tray contains the internal control, amplification reagent, enzyme and the probe-coupled superparamagnetic

particles for each *Candida* target. Two milliliters of the blood specimen is transferred to the T2Dx Instrument where lysis of the red blood cells, concentration and lysis of the *Candida* cells and amplification of the *Candida* DNA takes place. Amplification products are detected by T2MR detection using species-specific probes which are attached to the superparamagnetic particles. The assay identifies *Candida albicans* and/or *Candida tropicalis*, *Candida parapsilosis*, and *Candida glabrata* and/or *Candida krusei*. The test does not distinguish between *C. albicans* and *C. tropicalis*. The test does not distinguish between *C. glabrata* and *C. krusei*

Analytical Studies

Cross-reactivity was previously assessed in DEN140019. Additional cross-reactivity testing was performed in this submission using five organisms clinically relevant to pediatric populations: *Streptococcus agalactiae, Listeria monocytogenes, Haemophilus influenzae, Streptococcus mitis,* and *Neisseria meningitidis.*

Isolates were tested in triplicate at a concentration of 10^6 CFU/mL. Any organism that demonstrated cross-reactivity or gave an invalid result was further evaluated with additional replicates from two additional sample preparations at the same concentration and was tested at lower, more clinically relevant concentrations of organisms in blood (100-1000 CFU/mL).

Cross-reactivity was defined as an increase in the T2 signal above the established cutoff for the *Candida* detection channel when tested at clinically relevant concentrations. Cross-reactivity required both amplification of the organism with *Candida* primers and subsequent detection with any of the capture probes. Of the five organisms tested, two demonstrated cross-reactivity at 10^6 CFU/mL (*S. agalactiae, H. influenzae*). Cross-reactivity was not observed when the organisms were re-tested at 1000 CFU/mL. The remaining three organisms did not demonstrate cross-reactivity (**Table 1**).

Table 1: T2Candida Cross-Reactivity Results

Species	Concentration (CFU/mL)	Positive Results per Detection Panel			
		A/T	P	K/G	Internal Control
N. meningitidis	10^6 CFU/mL	0/3	0/3	0/3	Valid (3/3)
S. mitis	10^6 CFU/mL	0/3	0/3	0/3	Valid (3/3)
L. monocytogenes	10^6 CFU/mL	0/3	0/3	0/3	Valid (3/3)
S. agalactiae	10^6 CFU/mL	0/3	0/3	1/3	Valid (3/3)
	10^6 CFU/mL*	0/6	0/6	1/6	Valid (6/6)
	1000 CFU/mL	0/3	0/3	0/3	Valid (3/3)
	100 CFU/mL	0/3	0/3	0/3	Valid (3/3)
	33 CFU/mL	0/3	0/3	0/3	Valid (3/3)
H. influenzae	10^6 CFU/mL	0/3	0/3	2/3	Valid (3/3)
	1000 CFU/mL	0/3	0/3	0/3	Valid (3/3)
	100 CFU/mL	0/3	0/3	1/3	Valid (3/3)
	100 CFU/mL*	0/6	0/6	0/6	Valid (6/6)
	33 CFU/mL	0/3	0/3	0/3	Valid (3/3)

A/T = *C. albicans/ C. tropicalis;* P = *C. parapsilosis;* K/G = *C. krusei / C. glabrata*

*For any cross-reactive result, two additional unique sample preparations were tested at the same concentration. Results were not considered cross-reactive if only one replicate demonstrated cross-reactivity.

Summary of Clinical Performance – Pediatric Subjects

Clinical data from existing studies were used to support the use of T2Candida 1.1 Panel in testing pediatric patient samples. Two (2) peer-reviewed publications were identified where the T2Candida 1.1 Panel was utilized to test pediatric patients and performance was compared to blood culture results. A total of 246 pediatric samples were evaluated in accordance with the T2Candida 1.1 Panel Instructions for Use over the course of the two studies. Patient ages ranged from 23 weeks to 17 years. Low prevalence (as determined by positive blood culture) was observed (1.2%). For all samples, estimates of sensitivity (PPA) ranged from 50-100% and specificity (NPA) ranged from 97-99%.

Results of these studies and the existing adult study data demonstrate acceptable performance of the T2Candida 1.1 Panel to detect *Candida albicans, Candida tropicalis, Candida parapsilosis, Candida glabrata* and *Candida krusei* infection.

Predicate Comparison

Table 2: Comparison Between T2Candida 1.1 Panel and Predicate Device

Characteristic	T2Candida 1.1 Panel (New Device)	T2Candida 1.1 (K173536) (Predicate Device)
FDA Product Code	PII, NSU	Same
Regulatory Classification	Class II	Same
Regulation Number	21 CFR 866.3960	Same
Intended Use/Indications for Use	T2Candida® 1.1 Panel and T2Dx® Instrument is a qualitative T2 Magnetic Resonance (T2MR®) assay for the direct detection of *Candida* species in K_2EDTA 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 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 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 positive and negative External Controls (T2Candida QCheck Positive Kit and the T2Dx QCheck Negative Kit) 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.	Same

Characteristic	T2Candida 1.1 Panel (New Device)	T2Candida 1.1 (K173536) (Predicate Device)
Patient Population and Exclusions	Labeled for adult and pediatric patients (excluding neonates)	Labeled for adult patients
Sample Type	A minimum of 3 mL whole blood collected in a 4 mL blood collection tube with K_2EDTA anticoagulant.	Same
Test Platform	T2Dx Instrument	Same
Reagent Trays	T2Candida 1.1 Test Reagents for detection of *Candida* species	Same
Test Cartridge Format	T2Candida 1.1 Test Cartridge and disposables	Same
Test Principle	Nucleic acid amplification followed by T2 magnetic resonance detection	Same

Conclusions

The submitted information in this premarket notification supports a substantial equivalence decision.