March 11, 2020

Quidel Cardiovascular Inc.
Rachael S. Williamson
Associate Director, Regulatory Affairs
9975 Summers Ridge Road
San Diego, CA 92121

Re: k200363
Trade/Device Name: Quidel Triage® TOX Drug Screen, 94600
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, LAF, DIS, JXM, JXO, DJR, DJG, LDJ, LFG
Dated: February 13, 2020
Received: February 14, 2020

Dear Rachael Williamson:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
k200363

Device Name
Quidel Triage® TOX Drug Screen, 94600

Indications for Use *(Describe)*
The Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a fluorescence immunoassay to be used with the Quidel Triage® MeterPro for the qualitative determination of the presence of drugs and/or metabolites in human urine of up to 9 drug assays at or above the threshold concentrations. The threshold concentrations are provided below:

Abbreviation	Analyte	Calibrator	Cutoff
AMP	Amphetamines	d-Amphetamine	500 ng/mL
mAMP	Methamphetamines	d-Methamphetamine	500 ng/mL
BAR	Barbiturates	Butalbital	200 ng/mL
BZO	Benzodiazepines	Temazepam	200 ng/mL
COC	Cocaine	Benzoylecgonine	150 ng/mL
EDDP	Methadone Metabolite	EDDP	100 ng/mL
OPI	Opiates	Morphine	300 ng/mL
THC	Cannabinoids	11-nor-9-carboxy-Δ9-THC	50 ng/mL
TCA	Tricyclic Antidepressants	Desipramine	1000 ng/mL

This test provides only a preliminary test result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography / Mass Spectroscopy (GC/MS), Liquid Chromatography / Mass Spectroscopy / Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods.

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.

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K200363

1. 510(K) SUMMARY

1.1. Date Prepared:

February 13, 2020

1.2. Purpose for Submission:

Modification to Existing Device

1.3. Measurand:

Amphetamine, Methamphetamine, Barbiturates, Benzodiazepines, Cocaine, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), Opiates, Cannabinoids, Tricyclic Antidepressants

1.4. Type of Test:

Qualitative, lateral flow immunofluorescence

1.5. Applicant:

Quidel Cardiovascular Inc.
9975 Summers Ridge Road
San Diego, California 92121
Telephone: 858-302-0334
Fax: 858-302-0334

Rachael S. Williamson (Submission Contact)

1.6. Proprietary and Established Names:

Quidel Triage® TOX Drug Screen, 94600

1.7. Regulatory Information:

Quidel Triage® TOX Drug Screen, 94600:

Product Code	Classification	Regulatory Section	Panel
DKZ	Class II	21 CFR 862.3100, Amphetamine test system	Toxicology (91)

Product Code	Classification	Regulatory Section	Panel
LAF	Class II	21 CFR 862.3610, Methamphetamine test system	Toxicology (91)
DIS	Class II	21 CFR 862.3150, Barbiturate test system	Toxicology (91)
JXM	Class II	21 CFR 862.3170, Benzodiazepine test system	Toxicology (91)
JXO	Class II	21 CFR 862.3250, Cocaine and cocaine metabolite test system	Toxicology (91)
DJR	Class II	21 CFR 862.3260, Methadone test system	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate test system	Toxicology (91)
LDJ	Class II	21 CFR 862.3870, Cannabinoid test system	Toxicology (91)
LFG	Class II	21 CFR 862.3910, Tricyclic antidepressant drugs test system	Toxicology (91)

1.8. Intended Use:

Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a fluorescence immunoassay to be used with the Quidel Triage® MeterPro for the qualitative determination of the presence of drugs and/or metabolites in human urine of up to 9 drug assays at or above the threshold concentrations. The threshold concentrations are provided below:

Abbreviation	Analyte	Calibrator	Cutoff
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EDDP	Methadone Metabolite	EDDP	100 ng/mL
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THC	Cannabinoids	11-nor-9-carboxy-Δ^9-THC	50 ng/mL
TCA	Tricyclic Antidepressants	Desipramine	1000 ng/mL

This test provides only a preliminary test result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography / Mass Spectroscopy (GC/MS), Liquid Chromatography / Mass Spectroscopy / Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods.

1.9. Device Description:

Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a single use test device and is used in conjunction with the Quidel Triage® MeterPro. The device contains murine monoclonal antibody conjugates and drug conjugates labeled with a fluorescent dye or immobilized on the solid phase and stabilizers. The testing device is inserted into and read by the Quidel Triage® MeterPro. Threshold concentrations are used to separate a negative result from a presumptive positive result.

1.10. Substantial Equivalence Information:

1. Predicate Device Name:

   Quidel Triage TOX Drug Screen, 94600

2. Predicate 510(k) Number:

   K182719, Quidel Triage TOX Drug Screen, 94600

3. Comparison with Predicate:

<table>
<tr><th>Item</th><th>Cleared Device</th><th>Modified Device</th></tr>
<tr><th>Features</th><th>Quidel Triage TOX Drug Screen, 94600</th><th>Quidel Triage TOX Drug Screen, 94600</th></tr>
<tr><td>Intended Use</td><td>The Quidel Triage TOX Drug Screen, 94600 is a fluorescence immunoassay to be used with the Quidel Triage MeterPro for the qualitative determination of the presence of drug and/or metabolites in human urine of up to 9 drug assays at or above the threshold concentrations.

The threshold concentrations are provided below:

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</table>

This test provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectroscopy (GC/MS), Liquid Chromatography/Mass Spectroscopy/Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods.</td><td>Same</td></tr>
</table>

Item	Cleared Device	Modified Device
Features	**Quidel Triage TOX Drug Screen, 94600**	**Quidel Triage TOX Drug Screen, 94600**
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Same
System Procedure	Sample is added to a single use test device which is then read by the instrument. The instrument measures fluorescence of discreet measurement zones for each assay. The instrument is designed to read multiple assays at the same time.	Same
Storage	2-8°C	Same
Specimen Type	Human urine	Same
Single-use Test Device	Yes	Same
Analyte Cutoffs (ng/mL)	AMP = 500 EDDP = 100 mAMP = 500 OPI = 300 BAR = 200 THC = 50 BZO = 200 TCA = 1,000 COC = 150	Same
Specificity Table	The four (4) additional compounds identified for the modified device were not included in the original 510(k) submission.	Four (4) additional compounds added to the Specificity Tables in the package insert. <u>BAR Specificity Table</u> • Metharbital • *p*-Hydroxyphenobarbital • Talbutal <u>BZO Specificity Table</u> • Alprazolam glucuronide-OH

1.11. Standard/Guidance Document Referenced:

None referenced.

1.12. Test Principle:

The Quidel Triage TOX Drug Screen, 94600 is a test device utilizing the standard Triage technology. It is a competitive fluorescence immunoassay which contains all the reagents necessary for the qualitative detection, relative to an assigned threshold value, of the major urinary metabolites for the following substances in human urine: amphetamine (AMP), methamphetamine (mAMP), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), methadone/methadone metabolite (EDDP), opiates (OPI), tetrahydrocannabinol (THC), and tricyclic antidepressants (TCA).

The Test Device contains:

- Murine monoclonal antibodies against 9 targeted drugs or metabolites
- Fluorescently labeled antibodies
- Fluorescently labeled metabolites
- Solid phase
- Stabilizers

The test procedure involves the addition of a urine specimen to the sample port on the Test Device. After addition of the specimen, the urine passes through a filter. The specimen reacts with fluorescent antibody conjugates or with fluorescent drug conjugates and flows through the Test Device by capillary action. The presence of drug or drug metabolite in the urine specimen prevents binding of the fluorescent conjugates to the solid phase on the detection zone. Excess urine washes the unbound fluorescent conjugates from the detection lane into a waste reservoir.

The Test Device is inserted into the Quidel Triage MeterPro. The Quidel Triage MeterPro is programmed to perform the analysis after the specimen has reacted with the reagents in the Test Device. The analysis is based on the amount of fluorescence the Quidel Triage MeterPro detects within a measurement zone on the Test Device. The positive or negative results are displayed on the Quidel Triage MeterPro screen in about 15 minutes. All results are stored in the Quidel Triage MeterPro memory to display or print when needed. If connected, the Quidel Triage MeterPro can transmit results to the laboratory or hospital information system.

1.13. Performance Characteristics:

1. Analytical Performance

    a. Precision/Reproducibility:

    Not applicable. This parameter was assessed under K182719.

b. Linearity/Assay Reportable Range:

Not applicable. These devices are intended for qualitative use only.

c. Traceability, Stability, Expected Values

Not applicable. This parameter was assessed under K182719.

d. Detection Limit:

Not applicable. This parameter was assessed under K182719.

e. Analytical Specificity:

To test cross-reactivity, drug metabolites and other compounds that may be present in human urine samples were tested on Quidel Triage TOX Drug Screen, 94600 Test Devices. The following is a summary of the cross-reactivity study for four (4) additional compounds that were tested and analyzed in the same manner as the other compounds assessed under K182719.

BAR (Cutoff = 200 ng/mL)	**Results Positive at (ng/mL)**	**% Cross-Reactivity**
Metharbital	1,000	20.0
p-Hydroxyphenobarbital	700	28.6
Talbutal	200	100.0

BZO (Cutoff = 200 ng/mL)	**Results Positive at (ng/mL)**	**% Cross-Reactivity**
Alprazolam glucuronide-OH	1500	13.3

f. Assay cut-off:

Not applicable. This parameter was assessed under K182719.

2. Comparison studies:

a. Method comparison with reference method:

Not applicable. This parameter was assessed under K182719.

b. Matrix comparison:

Not applicable. These devices are for use with human urine samples only.

3. Clinical studies:

    a. Clinical sensitivity:

    Not applicable.

    b. Clinical specificity:

    Not applicable.

    c. Other clinical supportive data (when a. and b. are not applicable):

    Not applicable.

4. Clinical cut-off:

    Not applicable.

5. Expected values/Reference range:

    Not applicable.

1.14. Conclusion:

The additional analytical specificity testing conducted for the Quidel Triage TOX Drug Screen, 94600 demonstrates the device remains substantially equivalent with the previously cleared Quidel Triage TOX Drug Screen, 94600 (K182719).