SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

k200363

B Applicant

Quidel Cardiovascular Inc.

C Proprietary and Established Names

Quidel Triage® TOX Drug Screen, 94600

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
LAF	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
JXO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
DJG	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
LFG	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own Class II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for:**

   Product labeling to include the percent cross-reactivity of four drug metabolites that may be present in human urine samples, but not previously tested for cross-reactivity:

   - Metharbital, p-Hydroxyphenobarbital, and Talbutal for the Barbiturates assay.
   - Alprazolam glucuronide-OH for the Benzodiazepines assay.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.