510(k) Summary

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Sponsor and Correspondent:

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Device Identification:

Trade or Proprietary Name: Rapid TOX Cup II
Common Name: Urine Drug of Abuse Rapid Screening Test
Device Class: Class II
Panel: Toxicology

Product Classifications and Regulation Section:

LAF	Methamphetamine	21 CFR 862.3610			
DIO	Cocaine	21 CFR 862.3250	DJG	Opiates	21 CFR 862.3650
DJR	Methadone	21 CFR 862.3620	DIS	Barbiturates	21 CFR 862.3150
LDJ	THC/Cannabinoids	21 CFR 862.3870	JXM	Benzodiazepine	21 CFR 862.3170
DKZ	Amphetamine	21 CFR 862.3100	DJG	Buprenorphine	21 CFR 862.3650
LAF	MDMA	21 CFR 862.3610	DJG	Oxycodone	21 CFR 862.3650
LCM	Phencyclidine	Unclassified, 510(k) required	LFG	Tricyclic Antidepressants	21 CFR 862.3910

Substantial Equivalency

The Rapid TOX Cup II, a urine drug screen, is substantially equivalent to the Rapid TOX Cup (K073078). Table 2 compares the characteristics of the Rapid TOX Cup II (New Device) and the Rapid TOX Cup (Predicate Device). The table below gives a comparison of the new device with the predicate device.

	NEW DEVICE *Rapid TOX Cup II*	**PREDICATE DEVICE** Rapid TOX Cup
510(k) Number	N/A	K073078
FEATURES		
	SIMILARITES	
Classification Code	LAF, DIO, DJR, LDJ, DKZ, LCM, DJG, DIS, JXM, LFG	LAG,DIO, DJG, DJR, DKE, DKZ, JXM, JXN, LCM LFI
Device Class	II	II
Intended Use	**Rapid TOX Cup II** is a drug test that can detect 1 to 13 drugs in human urine. **Rapid TOX Cup II** is collection cup with a temperature strip attached. It contains an insert with one or more test strips in the insert. Each test strip can test for up to 4 different drugs. The test is for over-the-counter or professional use. **Rapid TOX CUP II** is a first step in a 2-step process. The test provides information about the presence of certain drugs in urine. The second step in the process is more specific testing by a laboratory. Amphetamines (d-amphetamine sulfate) (1000 & 500 ng/mL) Barbiturates (butalbital) (300 ng/mL) Benzodiazepines (oxazepam) (300 ng/mL) Buprenorphine (12.5 ng/mL) Cocaine (benzoylecgonine) (300 & 150 ng/mL) MDMA ((+/-) 3,4-methylenedioxy-methamphetamine) (Ecstasy) (500 ng/mL) Methadone (300 ng/mL) Methamphetamines ((+)methamphetamine HCl) (1000 & 500 ng/mL) Opiates (morphine-3-b-D-glucuronide) (2000 & 300 ng/mL) Oxycodone (100 ng/mL) Phencyclidine (phencyclidine HCl) (25 ng/mL) THC/ Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid) (50 ng/mL) Tricyclic Antidepressants (nortriptyline) (1000 ng/mL)	Rapid TOX Cup ™ is a one-step, lateral flow immunoassay contained in a polypropylene cup for the simultaneous detection of abused drugs in urine. Rapid TOX Cup - is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels: Amphetamine 1000 ng/mL Amphetamine 500 ng/mL Methamphetamine 1000 ng/mL Methamphetamine 500 ng/mL 3,4-methylenedioxymethamphetamine (MDMA) 1000 ng/mL 3,4-methylenedioxymethamphetamine (MDMA) 500 ng/mL Buprenorphine 12.5 ng/mL Benzodiazepines (Oxazepam) 300 ng/mL Barbiturates (Butalbital) 300 ng/mL Oxycodone 100 ng/mL Methadone 300 ng/mL Phencyclidine 25 ng/mL Propoxyphene 300 ng/mL Opiates 300 ng/mL Opiates 2000 ng/mL Cocaine (Benzoylecgonine) 300 ng/mL Cocaine (Benzoylecgonine) 150 ng/mL Tricyclic Antidepressants (Amitriptyline) 1000 ng/mL THC/ Cannabinoids (11 norΔ9-THC-9-carboxylic 50 ng/mL acid) Rapid TOX Cup is intended for professional use. It is not intended for over-the-counter sale to non-professionals. This assay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas-chromatography/mass spectrometry (GC/MS).
Assay Results	Qualitative	Qualitative
	DIFFERENCES	
Intended use	Over-the-counter use and professional use	For professional use only
Intended users	Untrained Consumers and Trained Professionals	Trained Professionals

Intended Use

The Rapid TOX Cup II is an in vitro diagnostic drugs of abuse testing device intended for use in the qualitative detection of the following drugs of abuse testing in a human urine specimen:

Analyte	Calibrator Drug	Cutoff (ng/mL)
Amphetamines	D-amphetamine	1000
Amphetamines	D-amphetamine	500
Barbiturates (Butalbital)	Butalbital	300
Benzodiazepines (Oxazepam)	Oxazepam	300
Buprenorphine	Buprenorphine	12.5
Cocaine	Benzoylecgonine	300
Cocaine	Benzoylecgonine	150
MDMA	MDMA (Methylenedioxymethamphetamine)	500
Methadone	Methadone	300
Methamphetamine	D-methamphetamine	1000
Methamphetamine	D-methamphetamine	500
Opiates	Morphine	2000
Opiates	Morphine	300
Oxycodone	Oxycodone	100
Phencyclidine	Phencyclidine	25
Marijuana	11-nor-Δ9-THC-9-carboxylic-acid	50
Tricyclic Antidepressants	Nortriptyline	1000

The test is intended for over-the-counter use.

This assay may yield positive results when barbiturates, benzodiazepines, or tricyclic antidepressants are ingested at or above therapeutic doses. There are no uniformly recognized cutoff levels for barbiturates, benzodiazepines, or tricyclic antidepressants in urine. The assay is not intended to distinguish between prescription use or abuse of these drugs.

Rapid TOX Cup II provides only a preliminary analytical result. A more specific alternate method must be used in order to obtain a more confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are used.

Methodology

Each Rapid TOX Cup II test device contains test strips for drugs of abuse that are one-step immunoassays. The specifically labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine specimen. The test strip consists of a membrane strip with an immobilized drug conjugate. A colloidal gold-labeled antibody (mouse or rabbit) complex is dried at one end of the membrane.

A control line, comprised of a different antibody/antigen reaction (Goat Anti-Mouse or Goat Anti-Rabbit), is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the urine specimen, and therefore, it should be present in all reactions. In the absence of any drug in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the "test" area. The formation of two (2) visible lines (control and test lines) occurs when the test is negative or below the cut-off for the drug. When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. The formation of a control line and the absence of a test line are indicative of a preliminary positive result.

This assay provides a preliminary test result for several drugs simultaneously. A more specific alternative test method must be used to obtain a confirmed, analytical result. Gas chromatography / mass spectrometry (GC/MS) and Gas chromatography / mass spectrometry (tandem MS) (GC-MS/MS) are the preferred confirmatory assays. Alternatively confirmatory assays may be Liquid chromatography Mass spectrometry (tandem MS) LC-MS/MS or HPLC.

To demonstrate the performance of the Rapid TOX Cup II by untrained consumers, consumer study participants were recruited in a user study to test prepared samples, generate a result and interpret the result. A summary of study results is included in the table below.

Drug Name	Rapid TOX Cup II Result	Negative No Drug Present	Low Negative Less than 50% of the cutoff concen-tration	Near Negative Between 50% below the cutoff and the cutoff concen-tration	Near Positive Between the cutoff and 50% above the cutoff concen-tration	High Positive Greater than 50% above the cutoff concen-tration
AMP	POSITIVE	0	0	5	40	20
500 ng/mL	NEGATIVE	160	20	35	0	0
AMP	POSITIVE	0	0	1	40	20
1000 ng/mL	NEGATIVE	580	20	39	0	0
BAR	POSITIVE	0	0	3	40	20
300 ng/mL	NEGATIVE	860	20	37	0	0
BZO	POSITIVE	0	0	3	40	20
300 ng/mL	NEGATIVE	880	20	37	0	0
BUP	POSITIVE	0	0	2	40	20
12.5 ng/mL	NEGATIVE	860	20	38	0	0
COC	POSITIVE	0	0	2	40	20
150 ng/mL	NEGATIVE	160	20	38	0	0
COC	POSITIVE	0	0	1	40	20
300 ng/mL	NEGATIVE	580	20	39	0	0
MDMA	POSITIVE	0	0	4	40	20
500 ng/mL	NEGATIVE	80	20	36	0	0
MTD	POSITIVE	0	0	1	40	20
300 ng/mL	NEGATIVE	860	20	39	0	0
METH	POSITIVE	0	0	3	40	20
500 ng/mL	NEGATIVE	80	20	37	0	0
METH	POSITIVE	0	0	2	40	20
1000 ng/mL	NEGATIVE	500	20	38	0	0
OPI	POSITIVE	0	0	3	40	20
300 ng/mL	NEGATIVE	160	20	37	0	0
OPI	POSITIVE	0	0	3	40	20
2000 ng/mL	NEGATIVE	620	20	37	0	0
OXY	POSITIVE	0	0	1	40	20
100 ng/mL	NEGATIVE	860	20	39	0	0
PCP	POSITIVE	0	0	2	40	20
25 ng/mL	NEGATIVE	860	20	38	0	0
THC	POSITIVE	0	0	1	40	20
50 ng/mL	NEGATIVE	960	20	39	0	0
TCA	POSITIVE	0	0	2	40	20
1000 ng/mL	NEGATIVE	580	20	38	0	0

Statement of Safety and Effectiveness

The submitted information in the premarket notification is complete and supports a substantial equivalence for OTC use of the Rapid TOX Cup II.